Indiana State Department of Health
ATTACHMENT D

Lab Information Management System
Mandatory and Desirable Requirements

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Revision /Update: Version 2

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1. ISDH LIMS Project Overview

The ISDH Labs provide laboratory support services for a wide variety of local, state and federal law enforcement, emergency response, health and environmental protection programs. The state laboratory is at the core of the public health system linking almost every facet of the health infrastructure including food safety, disease control and prevention, maternal and child health. State laboratory data is also used to monitor the quality of air, water, food and the soil used to grow crops. The state laboratory is critical for a rapid response to biological and chemical agents used for illegal or terrorist activities. The ISDH Labs currently have multiple system processes that are disparate and not integrated. There is a critical need to implement a robust, integrated, comprehensive laboratory information management system (LIMS) that can securely gather, integrate, store and transmit data.

The ISDH Labs have approximately 119 staff in the Chemistry, Microbiology and Administrative sections. Most areas of the laboratory still receive requests on paper and record, report and file results on paper forms. ISDH Labs maintain a variety of database applications to track and sustain supply, kit and equipment inventories, sample submission and test result data. Most of these applications are outdated, not efficient and extremely labor intensive. For more information on ISDH Laboratory Services see http://www.state.in.us/doh/.

1.1 Project Scope

The ISDH intends to purchase a single, comprehensive turn-key Commercial Off the Shelf (COTS) LIMS, to include software, implementation support, training and data conversion tasks, as part of an ongoing program to improve efficiency in their laboratories; customized LIMS proposals will not be considered. The vendor shall be able to demonstrate the capabilities of its COTS LIMS with an already operational, integrated, comprehensive COTS LIMS product available for ISDH to review, in a Large Public Health Laboratory (LPHL) setting, with LPHL defined as a PHL serving a state, county or city with population comparable to Indiana (at least 4 million) and performing both clinical and environmental analyses. The vendor understands that the COTS LIMS product shall include appropriate modules to support collection, testing, reporting and quality assurance for clinical, environmental and food samples in a single system. This document includes information about the ISDH laboratory (and other integral) facilities and detail specific requirements for responding to the Request For Proposals (RFP) to provide LIMS COTS software, implementation support, training, and data conversion services. Proposals shall deal with the immediate needs of the ISDH and the long-term goals of the organization as set forth in this document.

The new LIMS will enable the ISDH Labs to communicate more efficiently with local, state and federal public health facilities for the purpose of disease prevention, control and surveillance as well as emergency response. This LIMS will allow secure electronic transmission of specimen collection data and results to and from ISDH Labs. This LIMS

will provide customers with immediate access to sample tracking information and completed results. It will facilitate the direct transfer of information from laboratory instrumentation to LIMS reducing data entry errors, saving labor time and allowing staff to take full advantage of current and future technologies. It will enable quality assurance/ quality control procedures to be built into the system for increased efficiency of error detection/prevention. The LIMS will allow for data archiving and ad hoc reporting. It will save ISDH Lab personnel time and reduce potential errors in data handling. Data can be integrated and evaluated. Data can be securely transferred and entered into national databases eliminating duplicated manual data entry processes. In addition, the maintenance tasks would be reduced for all staff using the current multiple disjointed systems.

2. Evaluation Strategy

The ISDH procurement strategy is to select a vendor that will provide a complete LIMS package, as outlined in this document, and negotiate a contract to configure, install, train users, and assist in the maintenance of the LIMS on the ISDH network.

ISDH evaluates Adherence to Requirements, Overall Management Judgment, and Price (sections 3.2.1, 3.2.2, and 3.2.4, respectively, of the RFP). Evaluation of these sections includes many factors, specifically four categories of information: administrative compliance, vendor responsibility, responsiveness and price. All offers, regardless of the type of solicitation, must meet the following administrative and responsibility criteria.

a) **Administrative Compliance.** ISDH will determine whether the response complied with the instructions for submitting proposals. IDOA must reject offers that are submitted late.

b) **Vendor Responsibility.** ISDH will determine whether the Vendor submitting the offer is one with whom ISDH can or should do business. Factors that ISDH may evaluate to determine "responsibility" include, but are not limited to: past performance, references, compliance with applicable laws, financial stability and the perceived ability to perform completely as specified. A Vendor must at all times have financial resources sufficient to ensure performance of the contract and must provide proof upon request. ISDH will determine whether any failure to supply information requested within the RFP and its attachments, or the quality of the information, will result in rejection.

c) **Evaluation of "responsiveness" and "price."** Responsiveness includes several factors but generally refers to how well the respondent addresses the requirements listed within the RFP and its attachments. Price will be scored based on all respondents' overall total proposed prices.

d) **Request for Proposals.** ISDH will determine how well responses meet requirements in terms of "responsiveness" to the specifications. ISDH will rank responses, without consideration of price, from best to least qualified

using a point ranking system as an aid in conducting the evaluation. References may be considered again in this portion of the evaluation. ISDH will determine whether any failure to supply information, or the quality of the information, will result in rejection or downgrading of the response. The "responsible" Offeror whose proposal meets "administrative" requirements and whose offer is most advantageous shall be eligible for award. If ISDH does not consider the price submitted in response to this RFP to be fair and reasonable and that price cannot be negotiated to an acceptable level, ISDH reserves the right to award to the next highest ranked vendor. ISDH will determine whether the price is fair and reasonable by considering the offer, including the vendor's qualifications, the vendor's reputation, all prices submitted, other known prices, the project budget and other relevant factors.

e) **Vendor Demonstrations.** The top three to five vendors (based upon the scores of their Proposed Technical Solution) will be invited to demonstrate their system for the evaluation team's review. The scoring system is outlined in Attachment E and in under Vendor RFP Response Protocol in this document. The demonstration shall follow a script, which will be provided to qualifying respondents (based on the source selection matrix). Receipt of the demonstration script does not, in any way, indicate selection as one of the finalists, but does indicate that the respondent meets all mandatory criteria in the RFP.

Vendor Qualifications
The vendor shall provide information about the business organization and the company's ability to provide the complete LIMS solution. Specifically, the vendor shall describe the following and submit the information in the format described above:

Product Background
The vendor shall provide information concerning the product that is being proposed for this project. Additionally, the vendor shall describe the software quality methodology followed during development of the proposed product.

Company Resources
The vendor shall provide information concerning the size of their company, how long they have been in business, and a numerical breakdown of staff (by skill) especially detailed in the areas of development resources, implementation resources, and technical support for the same COTS System being proposed for the ISDH. Technical support is defined as those resources available to assist ISDH should technical problems arise, and include Help-Desk support and staff dedicated to developing LIMS COTS product enhancements and upgrades. Additionally, the vendor shall provide information concerning general annual revenues and other related financial data for the ISDH selection teams' review.

Specific Experience
The vendor shall provide a list of **all** LIMS installed relevant to the requirements of this RFP. Include sufficient detail to demonstrate relevance. Additionally, the vendor shall provide information regarding the specific technologies the proposed product utilizes.

The vendor shall also provide a list of corporate and technical reference contacts for **all** Systems implemented, or currently in progress, within the **past two (2) years** utilizing the same software version that is proposed for the ISDH LIMS. The reference shall include a synopsis of work provided to each referenced client and include costs, start and completion dates and shall identify the implementation personnel (if any) being proposed for the ISDH task who participated in the reference task. The ISDH Source Selection Team reserves the right to contact previous vendor customers not specifically listed in the proposal.

In lieu of established corporate experience, the vendor personnel resumes must include references for previous experience in implementing COTS LIMS applications in a similar environment. Desired experience would include implementation in a Public Health organization.

Corporate Resumes
The vendor shall supply corporate resumes for each individual proposed to participate in the implementation of the ISDH LIMS project. The vendor shall indicate the proposed individual's percentage of time available to work on the ISDH project from the time of contract award until the installed LIMS has been fully implemented.

ISDH prefers a vendor implementation staff with functional experiences in laboratory operations and information technology tasks related to the LIMS product being proposed.

The vendor shall not change proposed project personnel for which a resume is submitted without the ISDH or their designated representative's prior approval.

Vendor RFP Response Protocol
The vendor shall provide responses to each of the requirements contained in the RFP using Attachment E, Source Selection Matrix (SSM). Requirements in the SSM are classified as:

MANDATORY (M)	- These requirements must be provided
DESIRABLE (D)	- These requirements are desirable

Note: Proposals that do not meet a mandatory requirement will not be further evaluated. The extent to which a requirement is met will be evaluated by the LIMS evaluation team and will be scored on a 1-10 sliding scale for each Mandatory and a 0-10 sliding scale for each Desirable requirement based on the quality of the technical solution provided in the proposal.

If the function is fully provided as described in the RFP, and does not require customization to your existing product (as of the date of the proposal), respond "YES" in the Provided column and reference the pages in the proposal where this is described in detail. If you believe that you substantially meet the requirement, or do so in a way that appears to be different than the RFP descriptive statement, answer "YES/CLARIFY", then explain the difference in the Comments block and reference the pages in the proposal that explain this in detail. Answer "NO" if you can not provide a requirement. All requirements and sub-requirements must be answered. Providing detail concerning how your product meets this requirement will enable the evaluation committee to best evaluate your product's capabilities. If the vendor does not address the requirement, a "does not comply" response will be assumed for evaluation purposes.

Keep in mind that the SSM is only a summary list of requirements. Interpretation of the vendor's fulfillment of the specific requirements of this RFP will be determined by the requirements set forth in this entire RFP and all associated requirements, not the Source Selection Matrix

ISDH assumes that unless otherwise stated, all of the requirements in SSM Appendix will be delivered turnkey. Shall a functionality requirement identified in this RFP be proposed as "not to be provided turn-key", the vendor shall so state in the "Comments" section of SSM for the requirement. The vendor shall provide an estimate of the resources required for ISDH to organically develop the functionality or to have the unsupported work contracted to another vendor / integrator.

3. Overview of ISDH Laboratories

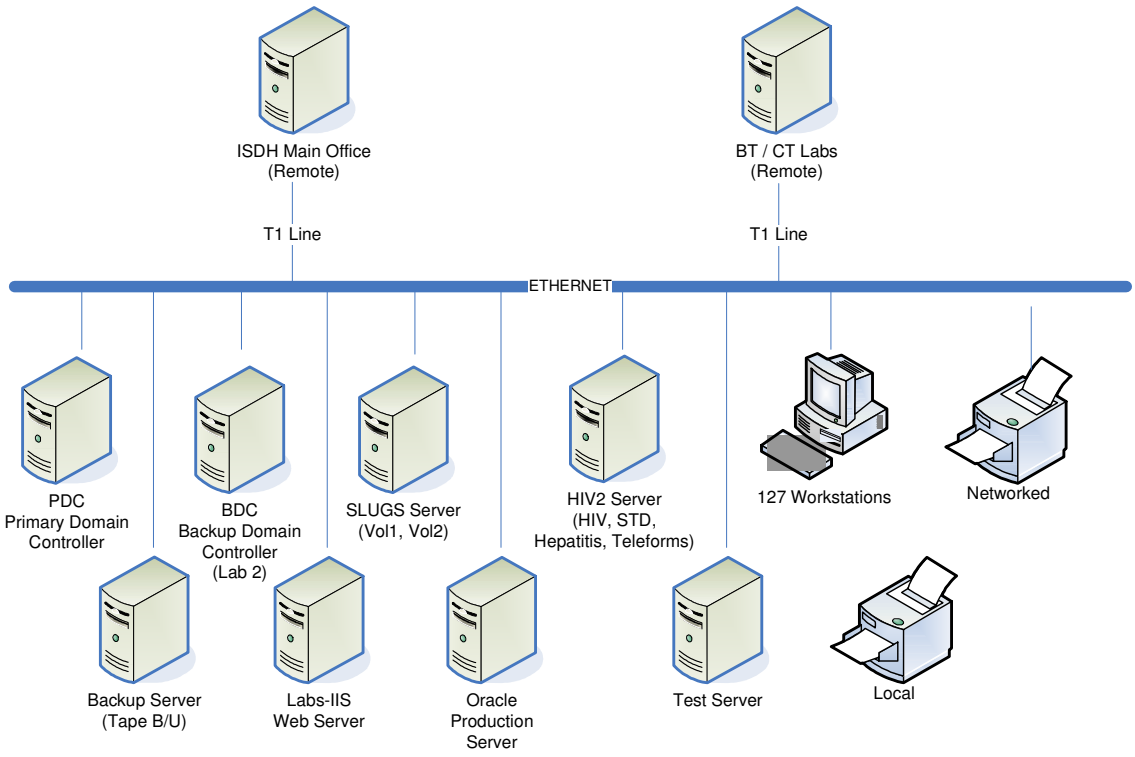
3.1. Current System Summary

3.1.1. Hardware at main laboratory facility, 635 North Barnhill.

- NetWare, NT2000 and , and NT2003 Servers currently installed
- Workstations – 127 networked (approx. half connected to instruments)
- Printers
  High-volume printers – Canon Copier (1), Sharp Copier (1)
  Medium-volume printers – Laserjet 8000n (2), Laserjet 5si (2)
  Specialty printers –
  Larger format -- HPDeskjet 1120c (1), HPDeskjet 1220c (2)
  Label printers (8)
  Workgroup printers –
  Jetdirect-connected -- HPLaserjet4 (2), HPLaserjet5 (2)
  Shared Windows printers – HPLaserjet4000, HP970c, Laserjet2000, HPLaserjet4 (2), HPLaserjet5 (1)

3.1.2. Software

- Email application is GroupWise 6.0 -- state-supported application
- Predominately use Oracle databases – Oracle 8 and Oracle 9i installed
  Migrating to Oracle 10g



3.2. Existing Data

- Eighteen (18) independent databases, developed in-house and used internally
  HIV and STD share submitter table which is synchronized manually
- Four external databases: UPS, PulseNet, PHLIS and eLEXNET

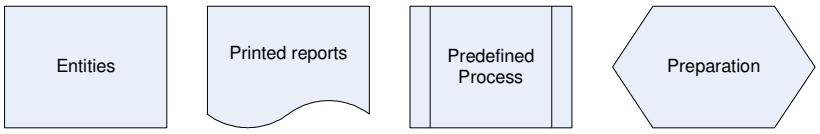
Database	Purpose	Functions	Application	Department(s)
Anthrax	Suspected Anthrax samples	Query & reporting	MSAccess XP	BioTerrorism
Clinical Containers	Containers shipped to various institutions for sample return	Data entry, query & reporting	MSAccess XP	Containers Area (Env Micro)
UPS	UPS labels for shipments	Create labels, query, reporting	UPS - Worldship 6.0	Containers Area
Hepatitis	Hepatitis test results	Query & reporting	MSAccess97, Oracle	Virology / Imm
Rabies	Rabies test results	Query &	MSAccess97	Virology /

Database	Purpose	Functions	Application	Department(s)
		reporting	(conv to MSAccessXP), Oracle db	Imm
Syphilis	Syphilis test results	Query & reporting	MSAccess97 (conv to MSAccessXP), Oracle db	Virology / Imm
Virology / Immunology	Virology/immunology test results	Query & reporting	MSAccess97 (conv. to MSAccessXP), Oracle db	Virology / Imm
Emicro	Environmental micro test results	Query & reporting	Visual FoxPro 6.0	Env Micro
STD	Sexually transmitted disease test results	Query & reporting	Visual FoxPro 6.0	Virology / Imm
HIV2000	HIV test results	Query & reporting	Visual FoxPro 6.0	Virology / Imm
Environmental Chemistry LIMS	Environmental laboratory results, quality control samples and related info	Query & reporting, significant reporting to IDEM (dept of env. mgmt)	Visual FoxPro 6.0	Gen Chem Metals Radio Chem Organic Chem Indoor Air
Consumer Health (Food Lab)	Test consumer complaints, surveillance on food and dairy for bacteria	Data entry, query & reporting	MSAccess97 (external db)	Consumer Health Micro (eLEXNET)
Consumer Health (Dairy Lab)	Test consumer complaints, surveillance on food and dairy for bacteria	Data entry, query & reporting	MSAccess97 (external db)	Consumer Health Micro (eLEXNET)
Consumer Health (Chemistry)	Meat analysis, consumer food complaints, pesticide analysis	Sample tracking, query & reporting	MSAccess97	Consumer Health Chem
Enterics	Study of pathogens, collect patient info	Data entry, manual reports	MSAccessXP	Clinical Micro (CDC)
Mycology	Study of pathogens, fungi; patient info	Data entry, manual reports	Excel 97	Clinical Micro
Special Reference	Study of pathogenic organisms	Data entry, manual	DbaseIII / MSAccess 97	Clinical Micro

Database	Purpose	Functions	Application	Department(s)
		reports		
Special Micro	Study of pathogenic organisms (microbiology)	Data entry, manual reports	DbaseIII	Clinical Micro
TB	Tuberculosis mycobacteria	Data entry, query, internal reporting	MSAccess97	Clinical Micro
Blood Lead	Blood lead testing and analysis	Data entry, query, internal reporting	MSAccess97	Clinical Micro

3.3. Current Workflows

A brief description of both current and anticipated workflows is provided below.

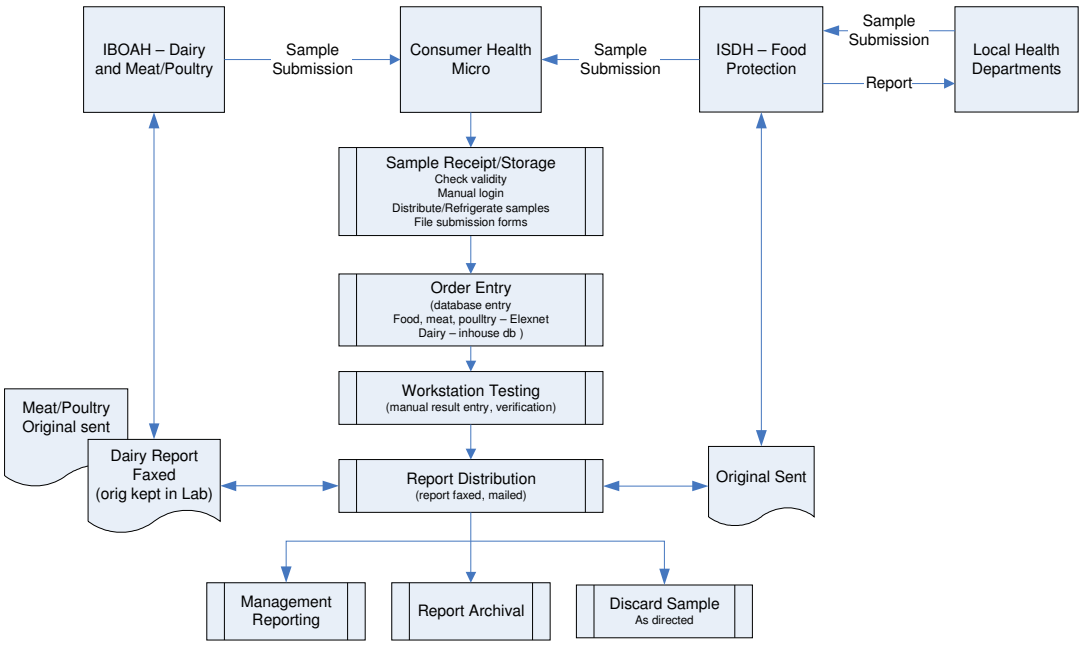


Legend for flow diagrams

3.3.1. Consumer Health Microbiology

- Internal Customers – Food Protection Program
- External Customers – Indiana Board of Animal Health (IBOAH) – Dairy Division and Meat and Poultry Division as well as local Health Departments
- Dairy – 188 samples/month; Food Protection and Meat/Poultry combined – 90 samples/month
- Samples are delivered by sanitarians or designated couriers, assigned a lab #. The data is entered into an ISDH database; eLEXNET imports data for the specific analytes/organism that they are monitoring.
- Samples are given individual numbers, which start at number one each fiscal year. Dairy samples have their own numbering system and Meat/Poultry and Food Protection are grouped together.
- Samples are placed in the appropriate area (refrigerator, freezer, or lab area) for testing.
- Original report sheets are kept in designated areas and copies made until time for final reporting. No worklists are utilized.
- Instruments: Charm 6600 and Bax (attached to computers), cryoscope, water activity meter and Charm Rosa Reader.

- Samples are analyzed and results are recorded on a worksheet and then transferred to the original request form. The analyst initials and reviews. For Meat/Poultry and Food Protection samples, the analyst enters the results into an internal database from which eLEXNET imports data for the specific analytes/organism that they are monitoring.
- The final report is reviewed/approved by a supervisor and then distributed to the submitter. (Reports are faxed to IBOAH and original is kept in lab).
- Photos are attached to reports in some instances.
- The submitter will return the report with sample discard instructions. Samples are discarded immediately if not requested for hold.
- Reports are archived on site for 3 years and off site for an additional 4 years.
- Management reports: weekly update to Food Protection, monthly summary of inhibitory tests, monthly report of all dairy samples and tests run.
- Regulatory Agencies: FDA and USDA.
- Certification / Licensing: FDA 2400 sheet guidelines for Dairy products.
- Special requirements.
- Photos as part of the report (ensure photo cannot be altered electronically).
- Capture internal comments that are not released with the final report.
- Group tests and ability to add optional test requests.
- Link of raw product to manufactured product (collected at same time from same dairy).
- FDA 2400 series guidelines, FDA BAM and USDA procedures.
- Sample labels that withstand moisture/heat/freezer cold (-20 C).



Note: Local County Health Departments submit samples to the ISDH Laboratory thru the ISDH Food Protection Program. Similarly, the results are reported back to the LCHD thru the ISDH Food Protection program.

3.3.2. Clinical Microbiology

- Customers: Local (County, City) Health Departments, Hospitals, Diagnostic Labs, Physician Offices, and sometimes general public
- Clinical Microbiology is comprised of several departments: Mycobacteriology (TB), Mycology, Reference, Special Reference, Enteric & Parasitology, Blood Lead, Media/Reagents
- Volumes
    - Mycobacteriology (TB): average=15/ day, 3300/year; peak volume=40/day; peak time=morning
    - Mycology: average=0-5/ day; peak volume=15/day; peak time=early spring/fall
    - Reference: approximately 300/year, sporadic sample volumes
    - Special Reference: varies from day to day, especially during an outbreak
    - Enteric & Parasitology: average=20/day
- Types of samples/containers: clinical specimens (human body fluids, swabs), bacterial isolates (agar slants, MGIT, ESP, Pellet, Bactec bottle)
- Internal and external customers request submission kits from the Containers area. Each microbiology area has its own submission form.
- The Microbiology Department has a sample receiving area serving all the microbiology departments.

- Samples are delivered to the sample receiving area via US mail, FedEx, UPS, courier or in person. Submissions are assigned a unique # (based on lab department), logged in the appropriate database and entered in manual log. Some submissions, such as enterics, rabies and TB, are entered into PHLIS (CDC database). The specimens and submission forms are labeled and either picked up by or delivered to the individual areas. MGIT tubes for TB are labeled with a bar code.
- Fresh specimens must be plated/processed within a specified time. Other samples are refrigerated or otherwise stored until processed.
- Worklists are not used, but submission forms are used as the bench sheet in most areas.
- If instruments are used for analysis, batches are defined in the instrument's computer with the samples identified by the Lab ID. The analyst reviews the results from the instrument print out and the QC information.
- Results are handwritten on the submission form and entered in the area database.
- Some areas report preliminary findings, if warranted, via phone call or Fax. All final reports are reviewed by a senior analyst or supervisor before being released for distribution.
- The clerical staff mails and/or faxes the final reports.
- Reports are archived on site for 3 years and off site for an additional 4 years.
- Isolates are saved, as long as storage space allows, (to be used for confirmation) in liquid nitrogen storage. Details are handwritten on reference cards.
- Management reports include
    - Monthly reports – type of tests performed, # of specimens/isolated received, tabulation of final results, QC, QA (using Excel)
    - Yearly reports for CDC grants
    - Genotyping reports
    - Turn-around-time
    - CLIA reporting (if problem occurs)
    - Results to ISDH Epi Disease area
- Regulatory agencies: CLIA
- Certification / licensing: CAP surveys, proficiency samples (twice/year); PFGE analyst certification by CDC.

Blood Lead

- Samples received in special mailer via the Childhood Lead Poisoning Prevention Program (Maternal/Child Health) downtown.
- Samples are logged in manually and the forms are returned downtown for database entry.
- The batches are defined in the instrument's computer with the samples identified by the Lab ID. The analyst reviews the results from the

instrument print out and the QC information. Upon approval, the analyst initiates the download of results from the instrument into the database.

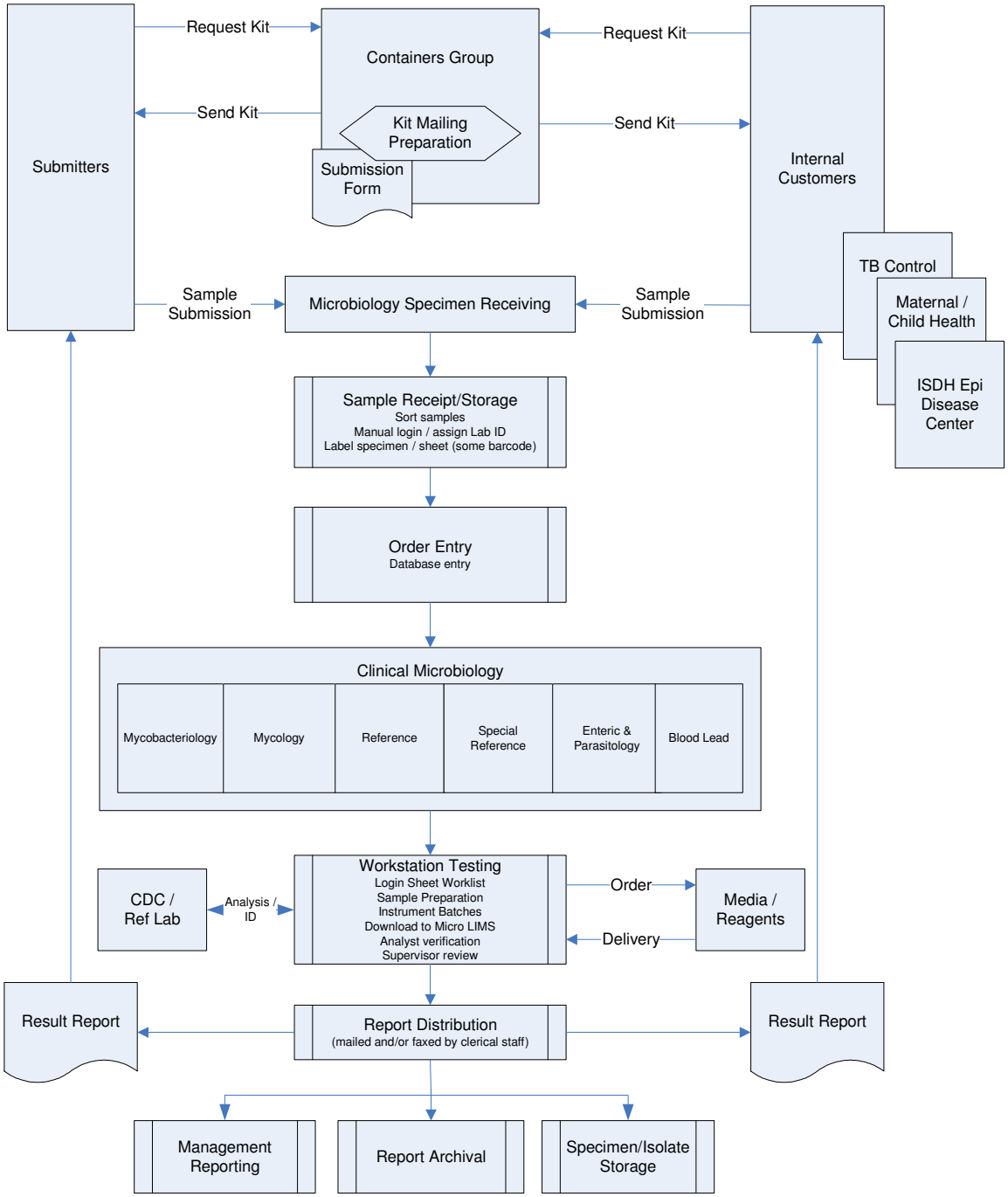
- Reports are printed and distributed by the downtown program sponsor. This group also enters the results into the STELLAR database.

Media & Reagents

- Orders for media and reagent preparation are received from various lab areas via handwritten form or email request.
- All recipes, identified by number, are stored in loose-leaf binders.
- The technicians track supply levels and reorder via the ISDH purchasing process.
- Prepared media and reagents are delivered to the requesting area.
- Each lab area is responsible for its own QC.

Requirements/desires

- ❖ Tracking for container shipments
- ❖ Inventory tracking of dry/frozen/wet ingredients
- ❖ Online recipe book
- ❖ Digital (diagnostic quality) image downloads
- ❖ Worklists
- ❖ Pending results listing
- ❖ Inventory system for stored isolates
- ❖ Online QC and equipment records
- ❖ Network Fax capabilities for reporting
- ❖ Specimen tracking (freezer location)
- ❖ Document specimen/isolate sent to CDC or other reference lab
- ❖ PFGE testing – download to CDC and PulseNET


Submitters
Request Kit
Send Kit
Containers Group
Kit Mailing Preparation
Submission Form
Request Kit
Send Kit
Internal Customers
TB Control
Maternal / Child Health
ISDH Epi Disease Center
Sample Submission
Microbiology Specimen Receiving
Sample Submission
Sample Receipt/Storage
Sort samples
Manual login / assign Lab ID
Label specimen / sheet (some barcode)
Order Entry
Database entry
Clinical Microbiology
Mycobacteriology
Mycology
Reference
Special Reference
Enteric & Parasitology
Blood Lead
CDC / Ref Lab
Analysis / ID
Workstation Testing
Login Sheet Worklist
Sample Preparation
Instrument Batches
Download to Micro LIMS
Analyst verification
Supervisor review
Order
Delivery
Media / Reagents
Result Report
Report Distribution
(mailed and/or faxed by clerical staff)
Result Report
Management Reporting
Report Archival
Specimen/Isolate Storage

3.3.3. Environmental Microbiology (and Containers)

3.3.3.1. **Containers Group**

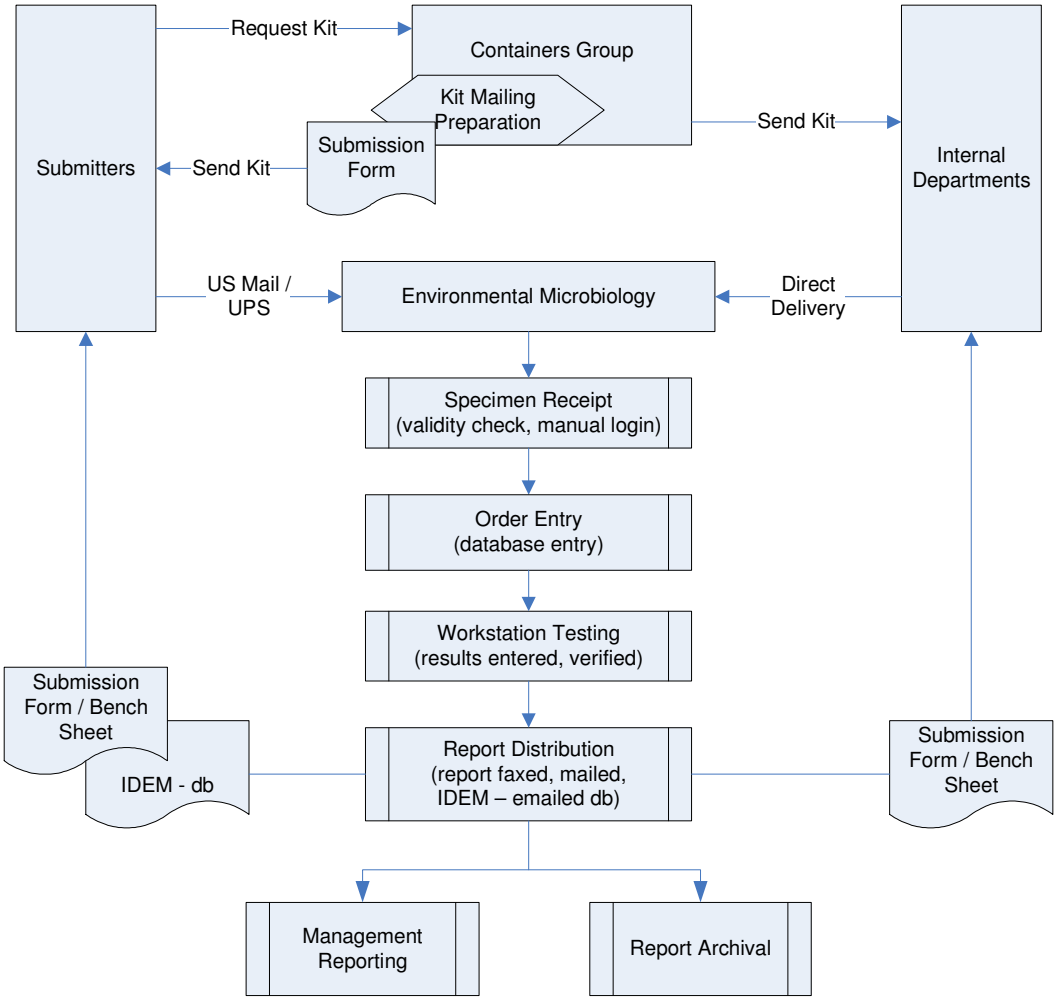
- Maintains inventory of shipping containers, specimen containers and submission forms for sample collection
- Sample kit bar-coded when sent out
- Requests for sample collection kits are received via email and phone
- Sends out 80,000 to 100,000 environmental and clinical sample kits per year via UPS (utilizing UPS tracking system to generate labels for the sample kits)
- Internal customers:
  - Clinical microbiology, environmental microbiology, virology/immunology, environmental chemistry, sanitary engineering, dental division, retail & manufactured food
- External customers:
  - Public water supplies, county health officials, other state agencies, clinics, dentists, MDs, private individuals, businesses, schools
- The samples received consist of drinking, pool, and surface waters, as well as water from bathing beaches and ice.
- Containers flow charts are incorporated into each area's flow charts. See flow charts in sections: 3.3.2, 3.3.3, 3.3.4, and 3.3.8.

3.3.3.2. **Environmental Microbiology**

- Internal customers:
  Sanitary engineering, dental division, retail & manufactured food
- External customers:
  Public water supplies, county health officials, other state agencies, private individuals, businesses, schools
- Sample volumes: 2,000 to 2,500 samples per month
- Submission forms are received in hard copy form. Nothing is submitted electronically.
- Submission forms contain submitter specific data and sample collection information
  - Health Official/Pools & Spas/Beaches & Lakes Report
  - Public Water System Report
  - Private Water Supply Report
- Samples received in the laboratory are checked for validity, matched with accompanying paperwork, sorted into groups,

assigned a laboratory identification number (serial number) and stamped with receipt date/time *(EPA requires that the sample be set up within 2 hours of receipt in the laboratory and incubation date/time).*

- Sample is logged in the Emicro database (see IT applications table, in 3.2).
- Worklists are not generated -- submission form is used as the bench sheet.
- Results are written on the bench sheet and manually entered in the Emicro database.
- Errors detected prior to reporting are corrected on the hard copy – initialed, dated and reason noted and changed in the database.
- Positive samples require repeat testing -- monitored and managed by the submitter.
- Positive results are faxed to the submitter
- QA/QC done manually.
- No checks and balances to verify all sample results reported back to the submitter.
- IDEM mandates scheduled reporting.
- Separate database sent monthly to IDEM.
- Submission form/bench sheet is copied and mailed to the customer.
- If fee required, report held until payment is received (exception made in case of positive result, due to health risks) – payment due letters mailed.
- Paper reports are archived by the Forms Center and maintained for a total of 5 years (only 2 years in house). Hard copy retrieval is required.
- Database results are archived automatically every month, with 4 months in the active file.
- Management reports contain counts of determinations and counts of invalid sample submissions, counts of positive and negative results and number of total samples – monthly, annually.
- Regulatory agencies
    - US Environmental Protection Agency
- Certification
    - Certified once every 3 years by USEPA
    - Responsible for certification of approximately 50 private environmental micro labs.



3.3.4. Virology/Immunology

- Customers: Local Health Departments, private practice, Department of Correction, Counseling and Testing Sites (CTS), hospital, clinics, Department of Mental Health, Animal Control
- Annual Specimen Volumes:

HIV (Blood)	36,000		Syphilis	26,000
HIV (Oral Fluid)	13,000		Chlamydia/Gonorrhea	56,000
Hepatitis	28,000		Virology	870
Immunology	600		West Nile Surveillance	3,500
Rabies	1,800			

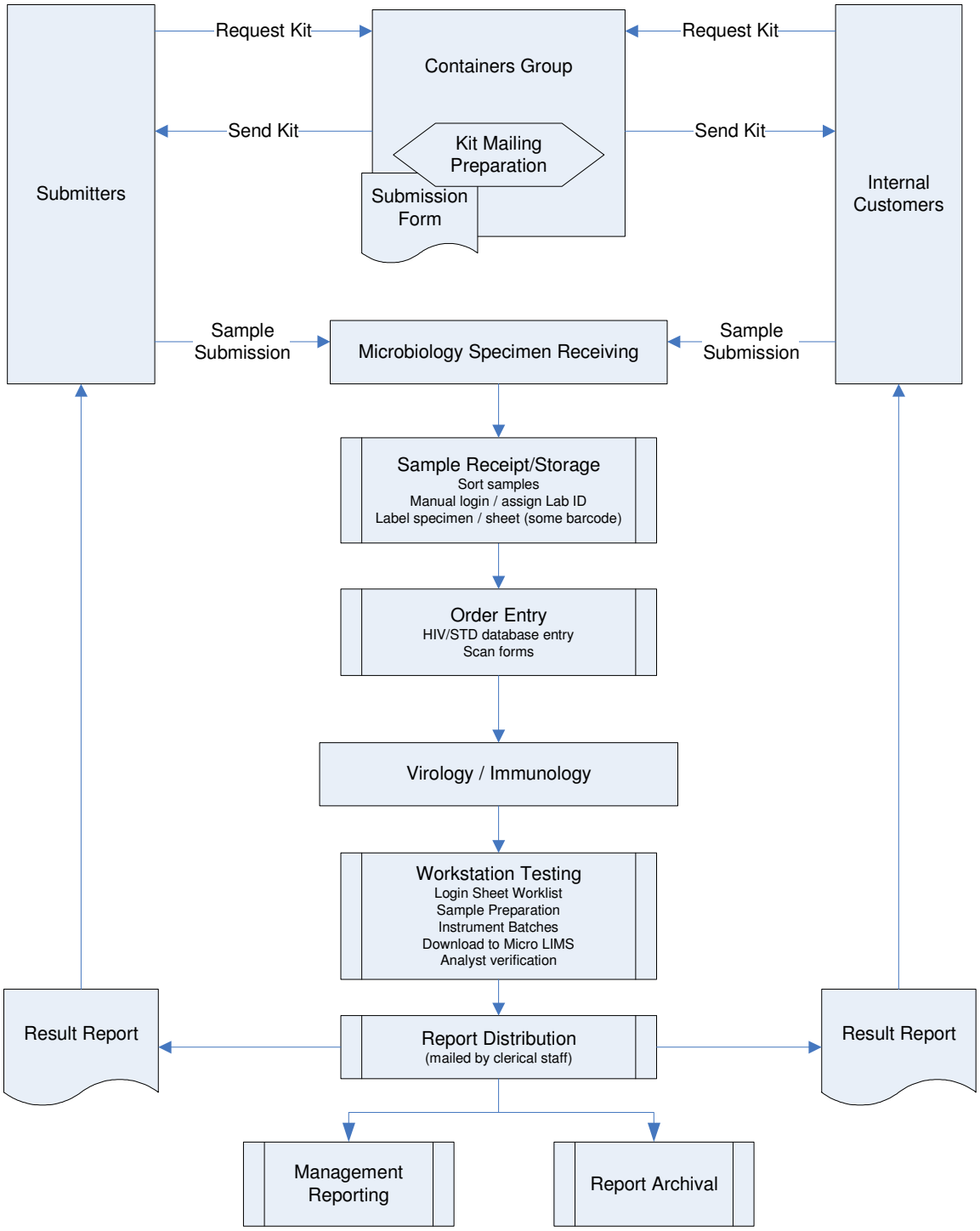
- Types of specimens: whole blood, oral fluid, serum, cerebrospinal fluid, brain tissue, stool, urine, and swabs from sources including cervix, urethral, rectal, throat and nasopharyngeal, animal heads and brain tissue.

- The Microbiology Department has a Specimen Receiving Room serving all the Microbiology/Immunology/Virology departments. Submitters request Kits and are provided with kits and submission forms.
- Samples arrive at Specimen Receiving Room (via mail or hand-delivered). The samples are sorted by the requested tests on the Submission Forms. A sequential Lab Number is assigned to each specimen according to the test requested and a label with the number affixed to the specimen and the Submission Form. Some of these labels have bar codes. (At the current lab location, some specimens, including rabies, syphilis and Chlamydia/Gonorrhea, are only sorted in the specimen receiving area. The initial processing is done in the same area where the analysis is performed. The new location will have a central specimen receiving area. It is anticipated that more initial processing will be performed there).
- Tests and methods are defined and requested at Specimen Receipt. Only HIV testing and Chlamydia/Gonorrhea use a computer system for Order Entry. The Submission Forms are scanned into an Imaging System that extracts data from the forms into a database. Other areas including rabies, syphilis and hepatitis are moving in that direction.
- In some areas the Analysts use the Log-In Sheet to create work lists, organize samples into batches, and begin sample preparation.
- Some tests set up the batches manually. For some other tests, the batches are defined in the instrument's computer with the samples identified by the Lab Specimen Number. The analyst reviews the results from the instrument print out and the QC information. Upon approval, the analyst initiates the download of results from the instrument into the Micro LIMS. (Currently only the HIV (serum) and the GC/CT results are electronically downloaded from the instrumentation and merged with the login information).
- Upon verification the microbiologist signs off the report and delivers the reports to the clerical staff for mailing to the submitters.
- Reports are archived in both electronic and hardcopy form and retained on-site for 3 years and off-site hardcopy for the mandated period.

o Special Requirements

- To capture QC data (Lot #, Expiration Date) electronically.
- Multiple mechanisms to distribute reports, e.g., Docs4Docs, Fax, electronic, printed copy.
- Sort printed reports by destination.
- Ability to check status of specimen testing and reporting.
- Ways to alert microbiologists of specimens nearing their stability period and their turn-around-time commitment.
- Order Entry screen should adapt to multiple Requisition (Submission) Forms.
- Generate work lists based on order entry.
- Generate lists of missing lab numbers to alert staff about the problem promptly.
- Container shipment -- Tracking system of received orders, filled orders, and an inventory of supplies needed to fill the orders.

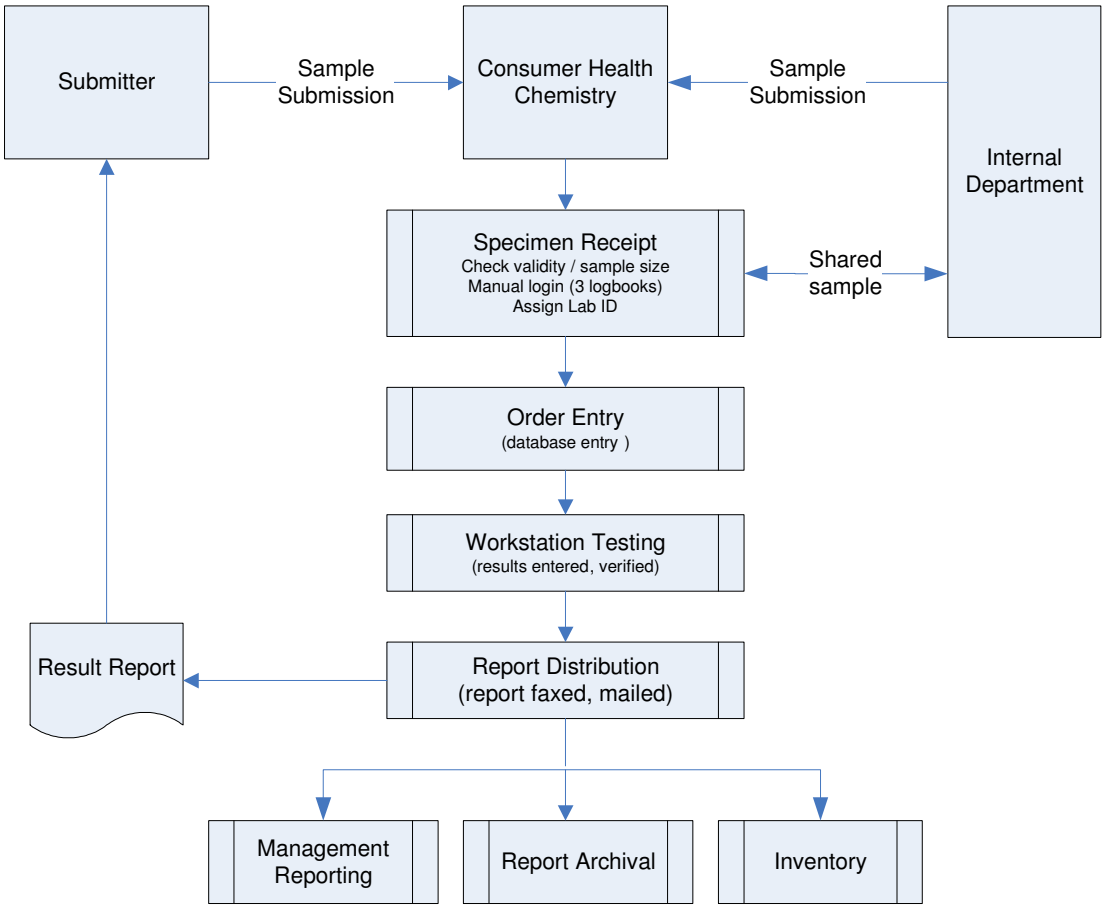
- Approximately 40,000 containers/kits were shipped last fiscal year.
- There are <500 submitters/customers ordering the shipping supplies.
- Management reports include:
    - Monthly reports – type of tests performed, # of specimens/isolated received, tabulation of final results, QC, QA (using Excel), including tabulation of number of specimens in a failed run.
    - Yearly reports for CDC grants
    - Genotyping reports
    - Turn-around-time
    - CLIA reporting (if problem occurs)
    - Results to ISDH Epi Disease area
    - Regulatory agencies: CLIA
    - Certification / licensing: CAP surveys, proficiency samples


Submitters
Request Kit
Containers Group
Request Kit
Send Kit
Kit Mailing Preparation
Send Kit
Internal Customers
Submission Form
Sample Submission
Microbiology Specimen Receiving
Sample Submission
Sample Receipt/Storage
Sort samples
Manual login / assign Lab ID
Label specimen / sheet (some barcode)
Order Entry
HIV/STD database entry
Scan forms
Virology / Immunology
Workstation Testing
Login Sheet Worklist
Sample Preparation
Instrument Batches
Download to Micro LIMS
Analyst verification
Result Report
Report Distribution
(mailed by clerical staff)
Result Report
Management Reporting
Report Archival

3.3.5. Consumer Health Chemistry

- Internal Customer: Food Protection (Consumer complaints from all counties)
- External Customers: Indiana Board of Animal Health – Dairy, Indiana Board of Animal Health – Meat and Poultry (IBOAH)
- Sample volumes depend on sanitarian; range approx 600/yr
- Customers submit samples in their own containers. IBOAH samples are received frozen with an IBOAH sample ID number on the label.
- Submission forms are received in hard copy form. Nothing is submitted electronically.
- Submission forms contain submitter specific data (can have multiple sub samples per submission form), sample collection information, and requested analysis. Additionally, lab specific data; lab ID, chain of custody, sample storage and disposal history.
    - Indiana State Board of Animal Health Meat and Poultry (IBOAH)
    - Indiana State Board of Animal Health Dairy (IBOAH)
    - Consumer complaints (Food Protection of the health departments)
- Shared samples are received with one submission form. Food Protection determines who gets the sample first (i.e. ice cream always goes to Micro first and is labeled with a micro lab id).
- Samples received are entered into three separate log books (consumer complaints, meat, dairy), each with its own numbering system (recycled at beginning of fiscal year – July 1).
- Handwritten labels are placed on the samples: internal id, route #, collection date/time and the IBOAH #. Meat samples may require sub-sample identification (i.e. 1006-1)
- Sample is entered in the Chemistry LIMS database. (See IT applications table in 3.2 above)
- No work lists are generated. Sample testing is run in batches and must be completed within management specified turn around time. (Pending list is generated each Monday)
- PCB samples have a management specified turn around time from collect to result.
- PCBs that exceed the regulation limits are in violation and further testing is required. Submitter is notified, a new container is provided and another sample is obtained (not matched to original collection in any way).
- Raw data from worksheets are placed into database to calculate the final answers and determine if answers are within the upper and lower boundary limits of violation. Also, database would print the word violation and the violation answer if one exists.
- Result reporting
    - Supervisor reviews data and written report for correctness -- supervisor and lab manager sign off

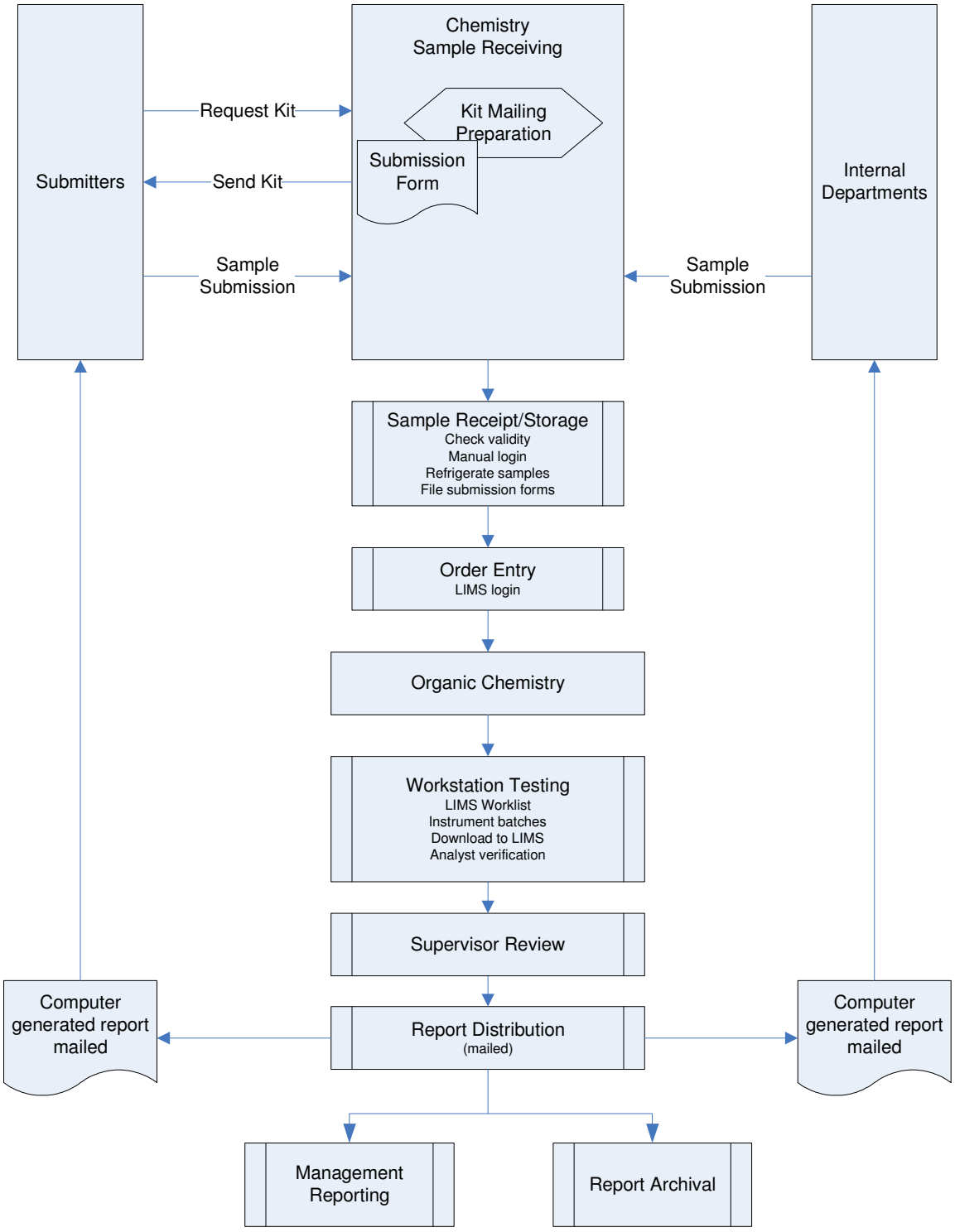
  - Reports contain written word, photos and numerical answers.
  - Original submission/result forms are sent to the submitter and copies are kept onsite.
  - If correction required after distribution, amended report is sent ("A" is appended to the lab #) and the submitter is called. The amended report contains the corrected report in its entirety. Original report is not included. The amended report is filed with the original report.
  - Consumer complaint reports are returned from the submitter with sample discard instructions. The discard instructions are placed in LIMS to generate a discard report.
- Management reporting
  - Weekly emailed reports
  - Progress report to managers
  - Status report to Food Protection
  - Status report to Board of Animal Health Meat and Poultry
  - Status report to Board of Animal Health Dairy
  - Paper reports
  - Monthly, fiscal year reports
  - Drug, chemical inventory
  - Samples to be discarded
  - Samples in violation
  - Ad hoc reporting – demographic reports (i.e. # of samples analyzed by submitter, type of sample, analyst, county of origin etc.)
- Report archival –
  - Physical reports stored 2 years on site and 5 years off site, then destroyed
  - LIMS files stored by fiscal year on server indefinitely (new database created each fiscal year)
  - Inventory control
  - Chemical and drug inventories
  - Ordering lab supplies
- Regulatory / Certification
  - FDA – maintain certification in the vitamin analysis of milk
  - USDA – maintain certification in the meat analyst program
  - NRC – for electron capture detectors Nickel 63 radio active
  - DEA – controlled substance registration certificate
  - State Health Professions Bureau – controlled substances registration certificate



3.3.6. Organic Chemistry

- Customers: County Health Departments, ISDH, and other state agencies
- Sample Volumes: VOC: 50 per month SVOC: 30 per month
- Types of samples/Containers: environmental samples (water, soil, sediment), food items
- The Chemistry Department has a Sample receiving area serving Environmental Chemistry. Submitters request containers from the Sample Receiving area and are provided with bottles and submission forms. IDEM furnishes its own bottles.
- Samples arrive at Sample Receiving, verified for appropriate volume and containers, logged in the Chemistry LIMS and in manual log, and identified with a unique number. The samples are labeled, and stored in the respective VOC or SVOC refrigerator. Submission forms are labeled with the unique sample number and stored in Sample Receiving. For multiple samples submitted on a single submission form, the Chemistry LIMS allows assignment of the samples into a Sample Delivery Group.
- Tests are defined by EPA method numbers and requested in the Chemistry LIMS.

- Analysts generate worklists from the Chemistry LIMS, retrieve samples from refrigerator, organize samples into batches, and begin sample preparation or analysis.
- The batches are defined in the instrument's computer with the samples identified by the Chemistry LIMS sample number. The analyst reviews the results from the instrument print out. Upon approval, the analyst initiates the upload of results from the instrument into the Chemistry LIMS.
- Analyst reviews, prints the report from the Chemistry LIMS and verifies results. Reports may be requested by Sample Delivery Group. For IDEM, the report includes QC information.
- Upon verification the supervisor signs off the report and delivers the reports for mailing to the submitters.
- IDEM requires electronic transfer of report data.
- Reports are archived in both electronic and hardcopy form. Hardcopy must be retained on-site for 3 years and a total of 10 years.

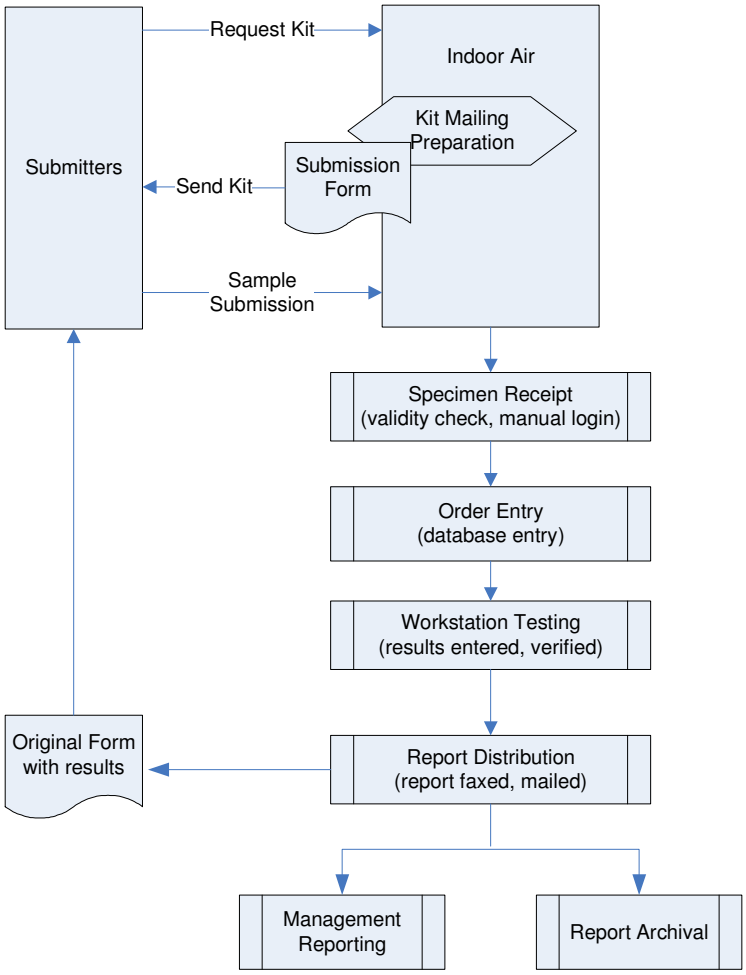

Chemistry
Sample Receiving
Kit Mailing
Preparation
Submission
Form
Submitters
Request Kit
Send Kit
Sample
Submission
Sample
Submission
Internal
Departments
Sample Receipt/Storage
Check validity
Manual login
Refrigerate samples
File submission forms
Order Entry
LIMS login
Organic Chemistry
Workstation Testing
LIMS Worklist
Instrument batches
Download to LIMS
Analyst verification
Supervisor Review
Computer
generated report
mailed
Report Distribution
(mailed)
Computer
generated report
mailed
Management
Reporting
Report Archival

3.3.7. Indoor Air

- Customers: ISDH Indoor Air investigators, County Health Departments, Indiana OSHA health inspectors (defunct program shifted to private lab), Indiana Bureau of Safety, Education, and Training (defunct program on extended hiatus)
- Types of Samples and Annual Volumes:

Air	259
Bulk	344
Paint	342
Other	1959

- Submitters telephone Indoor Air to request lead wipes and air sampling media kits and are provided with the kits and submission forms. Submission forms are available in the ISDH website.
- Samples arrive at Indoor Air by mail or walk-in, entered into Log-In Sheet, and identified with a unique Lab Study Number and a sub-number (12345-1) and hand labeled. The samples are logged into the lab tracking system (FoxPro DOS).
- Tests are identified by the receiving Analyst depending on the Submission Form and sample type received and ordered in the Chemistry LIMS
- Analysts are informed of the arrival of new samples or given the incoming submission forms, which they use to organize and prepare the samples for analysis.
- The samples are organized into Runs on a hand-written worksheet for the specific analyte (.e.g. Lead Paint). A results print out is generated from the instrument and the results copied onto the worksheet.
- The analyst signs off on the worksheet and copies the final result onto the submission form.
- Copies of the completed submission forms are retained and the originals mailed to the submitters. The copies are put in the “File” box. Completion of these forms is indicated by logging out the Sample Numbers from the handwritten LogIn Worksheet and the Sample Tracking System.
- Reports are archived in the file cabinet.

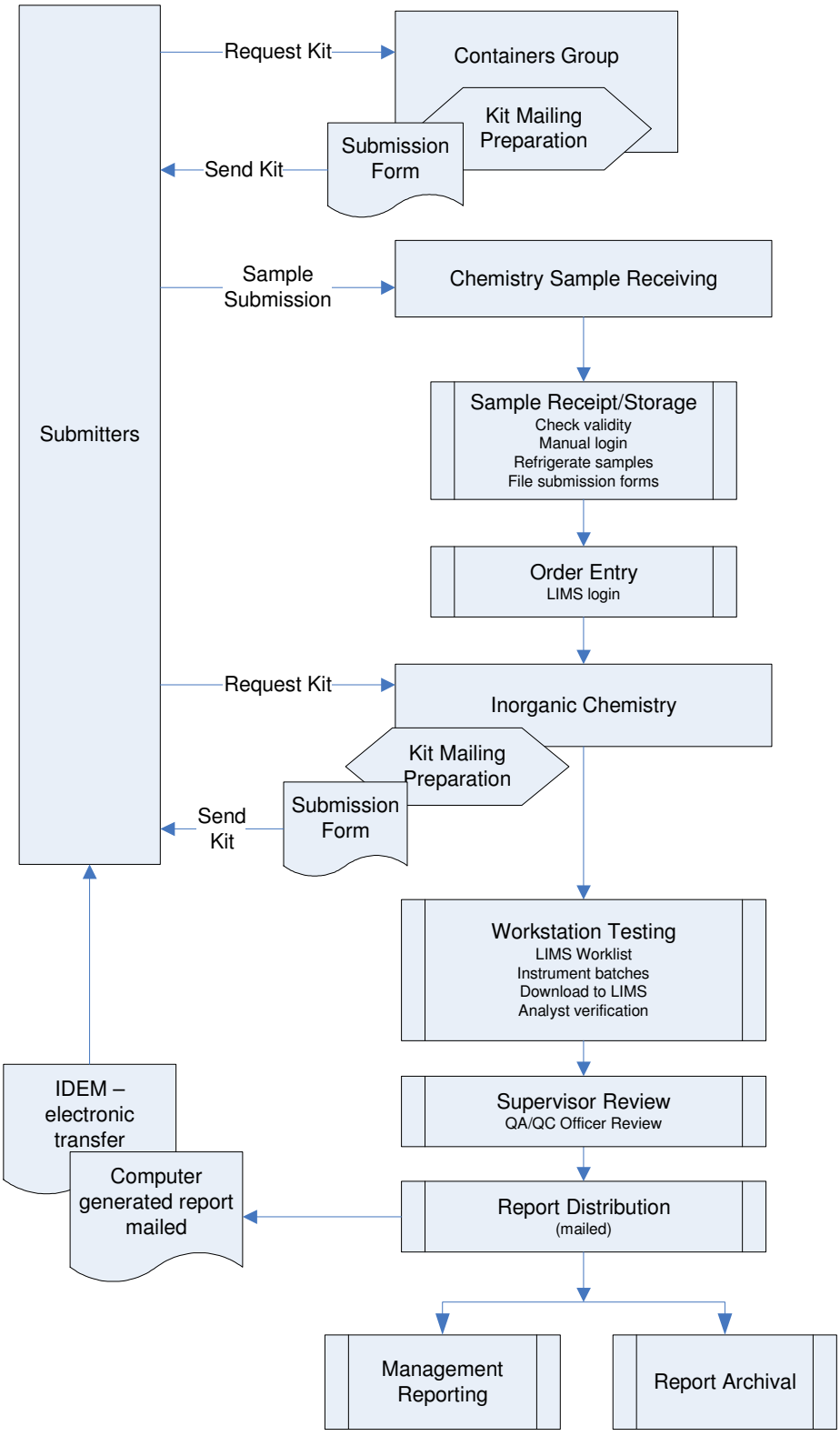


3.3.8. Inorganic Chemistry

- Customers: County Health Departments, Water Utilities, IDEM, other state agencies, private industry and individuals.
- Sample Volumes: 14,000 analyses per month.
- Types of samples: Liquids (rivers, streams, ditches, drinking water, monitoring wells, industrial waste, etc.), soils, sediments, and various types of consumer complaints.
- The Chemistry Department has a Sample receiving area serving all the Chemistry departments; mainly Inorganic and Organic Chemistry areas. Submitters request containers, except Water Test Kits, from Inorganic Chemistry and are provided with bottles and submission forms. The Containers department handles and fills requests for Water Test Kits. IDEM furnishes its own bottles.
- Samples arrive at Sample Receiving (via mail or hand-delivered). The samples are sorted by type of test (Metals, Nutrients, General, Cyanide), verified for appropriate volume and containers, pre-logged in the Chemistry LIMS (Lab Numbers reserved) and in Log-In book,

and identified with a unique Lab Number – color coded by type of test for easy identification. The specimens are labeled and stored in the respective refrigerator or Sample Storage Room. Submission forms are labeled with the Lab Number and stored in Sample Receiving. For multiple samples submitted on a single submission form, the Chemistry LIMS allows assignment of the samples into a Sample Delivery Group.

- Metal samples are preserved and sit for a certain number of hours before they are tested.
- Tests and methods are defined and requested in the Chemistry LIMS.
- Analysts generate worklists from the Chemistry LIMS, retrieve samples from refrigerator or Sample Storage Room, organize samples into batches, and begin sample preparation or analysis. The samples in the worklist are sorted by sample number or by viability (oldest collections first).
- The batches are defined in the instrument's computer or manually with the samples identified by the Chemistry LIMS sample number. The analyst reviews the results from the instrument print out. Upon approval, the analyst initiates the upload of results from the instrument into the Chemistry LIMS.
- The Receiving Agent prints the reports for review by analysts. Analyst reviews, prints the report from the Chemistry LIMS and verifies results. Reports may be requested by Sample Delivery Group. For IDEM, the report includes QC information.
- Upon verification the Receiving Agent prints the reports, the analyst signs off the report and the Receiving Agent delivers the reports for mailing to the submitters.
- IDEM requires electronic transfer of report data.
- Reports are archived in both electronic and hardcopy form. Hardcopy must be retained on-site for 3 years with 7 years archive for a total of 10 years.


Submitters
Request Kit
Containers Group
Kit Mailing Preparation
Submission Form
Send Kit
Sample Submission
Chemistry Sample Receiving
Sample Receipt/Storage
Check validity
Manual login
Refrigerate samples
File submission forms
Order Entry
LIMS login
Request Kit
Inorganic Chemistry
Kit Mailing Preparation
Submission Form
Send Kit
Workstation Testing
LIMS Worklist
Instrument batches
Download to LIMS
Analyst verification
Supervisor Review
QA/QC Officer Review
Report Distribution
(mailed)
IDEM – electronic transfer
Computer generated report mailed
Management Reporting
Report Archival

3.3.9. Radiochemistry

- Customers: ISDH, IDEM, IBOAH, FEMA, NRC, Public Water Supplies, Local and County Health Departments, Other state agencies
- Sample volumes: 900 samples per year
- Samples received by mail or walk-in in gallon containers or cubitainers labeled with the submitter information and collection date/time (paperwork provided by IDEM)
- Sample delivery to containers area by walk-in (IDEM water quality, aliquot) or directly to the Radiochemistry laboratory
- EPA requires that drinking water be preserved within 5 days of collection
- (EPA lab audit – auditor suggested notes to track problems with submissions past holding time)
- Tests requested/performed –
  drinking water – predetermined
  land quality – predetermined (may advise on specific situations)
  water quality – predetermined (fixed station monitoring)
  ISDH – varies (decided by radio chem.)
  Local health dept – varies (swipe samples)
  QC (internal and external)
- Sample identifiers:
  - LIMS system id (6-digit sequential #, system wide)
  - Lab id (4-digit sequential #, internal) – not reused yet
    Sample # (internal) written on container
    Samples are logged in – handwritten on log sheet and entered into LIMS system
  - Date received
  - Location
  - PWS ID#
  - Sample date/time
  - Submitter
  - Analyses
  - Method
  - LIMS#
  - Lab# (internal dept. id)
- Water quality worklist generated by LIMS system
  - Uranium
  - Radium – 228
  - Radium 226/228
  - Gross alpha/beta
- Worksheets
  - Radium 228 worksheet (wait for full batch to process)
    Batch # (from instrument, not stored in LIMS system)
    Date of sample
    Actinium ingrowth date/time

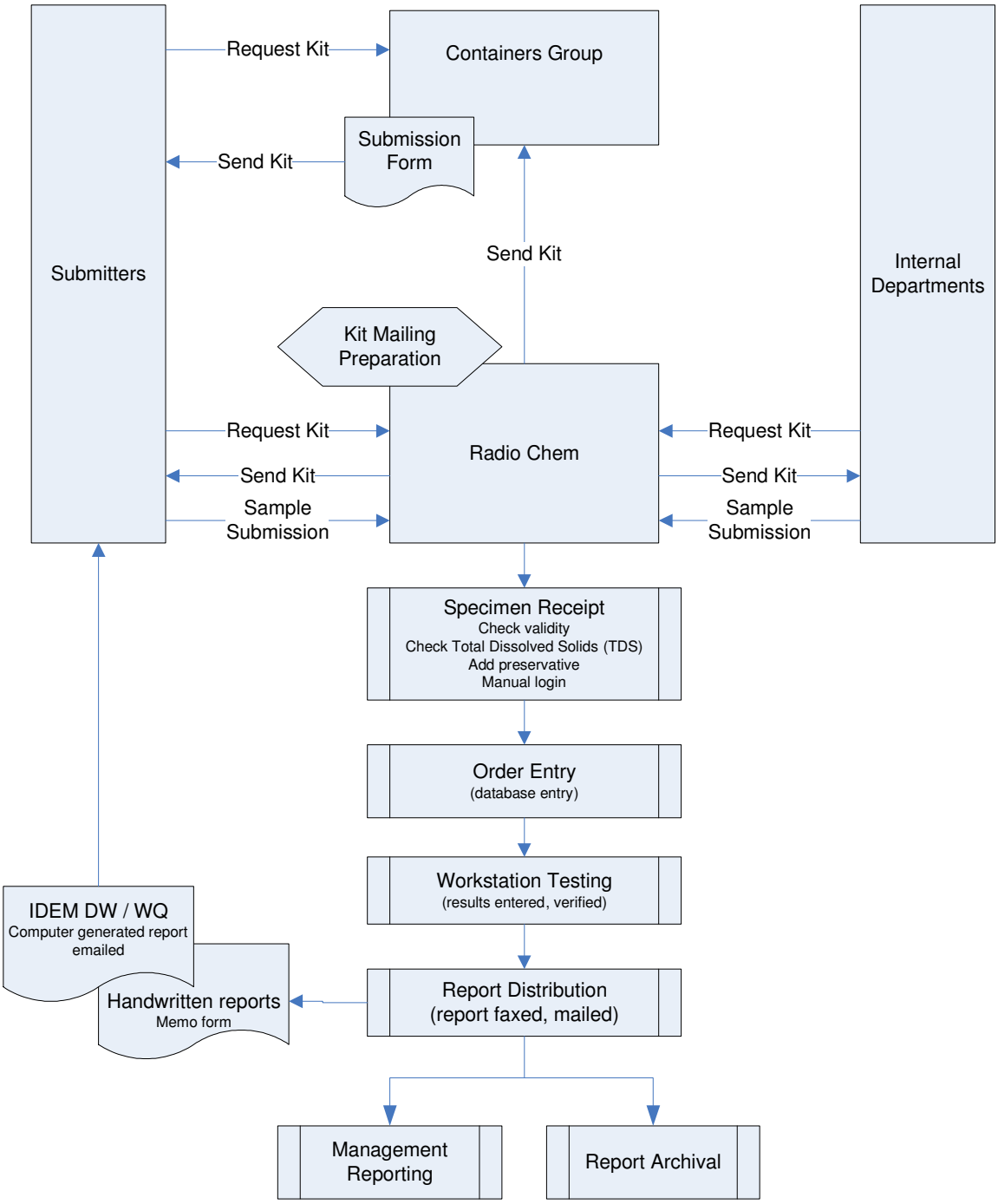
Actinium decay date/time
Sample # (lab id)
Collect date/time
Notes
Determinations (initial weight, final weight)
(samples first, stds. in back)

- Gross Alpha Beta worksheet
  Study Number
  Date
  Analysis Chemist
  Tennelec Run #
  Standard Used
  Sample # (LIMS id or Lab id)
  Sample volume (used for analysis)
  Planchet number (tracking # / rack # location)
  Initial weight (gm) and final weight (gm)

- Results entered in LIMS system are IDEM drinking water and water quality which are computer generated and emailed, or handwritten and mailed
- Preliminary results sometimes sent out prior to final report
- Paper reports are stored in file cabinet for 5-7 years
- Monthly and annual management report – sample volumes and determinations
- Regulatory agencies
  - EPA (drinking water)
  - Nuclear regulatory commission
  - FEMA
- Certification / licensing
  - EPA Drinking Water Certification
  - IUPUI Radiation Safety

Requirements:

- Prioritization of sample login / processing based on EPA requirements; deliver directly to Radiochemistry area (to preserve)
- Ability to track problems with submissions past holding time (EPA)
- Desire to maintain internal lab id (in addition to a LIMS id)


Submitters
Request Kit
Containers Group
Send Kit
Submission Form
Send Kit
Internal Departments
Kit Mailing Preparation
Request Kit
Send Kit
Sample Submission
Radio Chem
Request Kit
Send Kit
Sample Submission
Specimen Receipt
Check validity
Check Total Dissolved Solids (TDS)
Add preservative
Manual login
Order Entry
(database entry)
Workstation Testing
(results entered, verified)
IDEM DW / WQ
Computer generated report emailed
Handwritten reports
Memo form
Report Distribution
(report faxed, mailed)
Management Reporting
Report Archival

3.3.10. Bioterrorism and Chemical Terrorism

- The processes of these departments are still under development. For the most part, the workflow will follow the regular flow of the testing laboratory.
- Customers: All hospitals and clinic laboratories and first responders of a terrorism attack
- Types of Samples: unknown powders, environmental samples, clinical specimens/isolates
- Clinical BT/CT samples arrive to the testing laboratory using the same forms the lab normally uses. The Submission form should indicate that the submitted sample is a terrorism suspected sample. For these samples, additional information will be collected. Environmental BT samples/powders utilize a form specifically designed for those specimens. The samples must follow the Chain Of Custody procedure.
- The logging of samples, ordering of tests, testing, and reporting of results should follow the normal laboratory process.
- In the case of a positive or confirming result of a suspected terrorism sample, the designated person is informed to initiate the assigned procedure.

Special Requirements

- Under high volume circumstances, other laboratories outside ISDH may be used to maintain current with the demand. The LIMS should track the status of these samples.
- Because of the possible use of external laboratories, a new LIMS should adhere to the PHIN requirements for interoperability.

3.4. Current Instrumentation

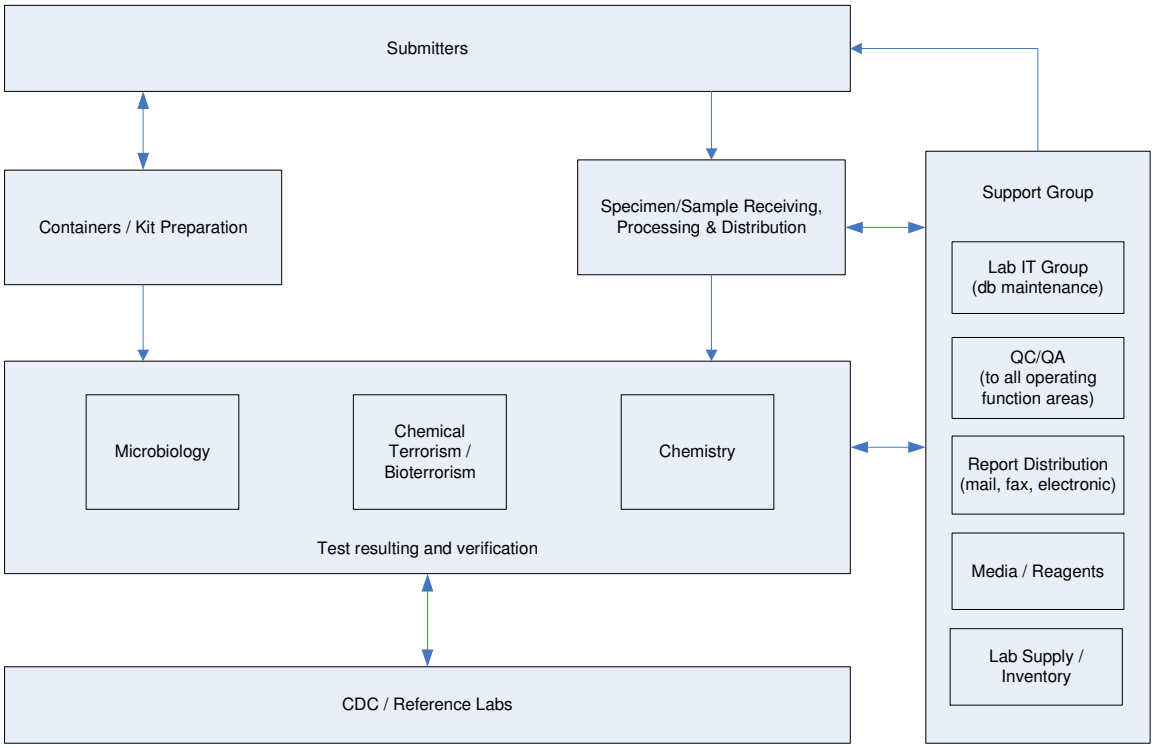
CONSUMER HEALTH LAB	**Software**
Spectrophotometer----FTIR--- Nexus Model 470	OMNIC v6.1a
Protein Analyzer---Leco FP528	FP528 v2.3
Gas Chromatograph—HP 5890 Series II	LC Chemstation A.06.03
Chromatograph----HPLC—HP 1100	LC Chemstation A.06.03
Chromatograph---GPC---OI AutoPrep 2000	WinSEP v2.3
INDOOR AIR LAB	**Software**
Spectrophotometer---AA—Varian Spectra AA 220 FS	SpectrAA 220FS v4.10PRO
Chromatograph----HPLC---Waters	Millenium 3.20
Chromatograph---IC---Dionex DX 120	PeakNet v5.1
Chromatograph---GC (FID and ECD)---Shimadzu GC-17A	CLASS-VP v4.2
Chromatograph—GC/MS—GC 17A/MSD QP 5050	CLASS-5000 v2.1
RADIOLOGICAL CHEMISTRY LAB	
Alpha Analyst---Canberra Model 7200-04	Genie-VAX
Gamma Analyzer—Canberra—MCA Genie	Genie-VAX v5.4
Gamma Analyzer—Canberra—MCA Genie	Genie-VAX v5.4
Alpha/Beta/Gamma Analyzer—Canberra S5-XLB	Eclipse v3.1
Alpha/Beta/Gamma Analyzer—Canberra S5-XLB	Eclipse v3.1
Alpha/Beta/Gamma Analyzer—Canberra S5-XLB	Eclipse v3.1
Alpha/Beta Analyzer—Canberra Tennelec Model LB 4110	OSUM v1.11
Alpha Beta Counter—Liquid Scintillation Counter—Packard Tri Carb 3100 TR	QuantaSmart v1.31
Analytical Balance---Mittler Model AX 204	none
INORGANIC ENVIRONMENTAL LAB	
Total Organic Carbon Analyzer—OI 1020 A	WinTOC 1020A v1.2
Mercury Analyzer—Leeman Labs PS200 II	AP/PS200II v4.2
Spectrophotometer—ICP—TJA Iris/AP	ThermoSpec v.2.2.1
Spectrophotometer—ICP/MS---Agilent 4500 Series 100	G1821C v C.01.01
Spectrophotometer---AA/Furnace---Perkin Elmer 5100	AA WinLab v2.61
AutoAnalyzer—(Hard., TKN, P)---Alpkem Flow Soln. IV	WinFlow 4.0
Total Organic Carbon Analyzer—Shimadzu TOC 5000A	TOC-Control v1.05.00

Analytical Balance---Sartorius MC 1	
AutoAnalyzer—(NH3, NO3, TKN)—Lachet Quick Chem FIA 8000 Series	Omnion FIA v2.0
AutoAnalyzer—(Cl, SO4, P, CN, NO3)---Alpkem Soln. III	EnviroFlow v3.0
AutoAnalyzer---(F, Alk.)---Lachat FIA Quick-Chem. 8000	Omnion v2.0
Spectrophotometer—Vis., Near IR, UV---(NO2, Hex. Cr, Si, Phenol)---Thermo Electron Corp. – Aquamate	none
ORGANIC ENVIRONMENTAL LAB	
Chromatograph—GC/MS—(VOC)— HP 6890 GC and 5973N MSD with purge & trap	MSD Chemistation D.01.02
Aglent HPLC 1100 with fluorescence and PDA	HPLC Chemstation
Chromatograph—GC/MS—Ion Trap—ThermoQuest/Finnigan 2000GCQ	Xcalibur v1.2 / ThruPut Target/NT v.4.12
Chromatograph—GC with TSD and ECD—Varian 3600 CX	Star Workstation v6.2
Chromatograph—GC with TSD and ECD—Varian 3600 CX	Star Workstation v6.2
Chromatograph—GC with 2 ECDs---Varian CP3800	Star Workstation v6.2
Chromatograph---HPLC---Waters	Millenium 3.20
Chromatograph—GC/MS—(SVOC)— HP 5890 II GC and 5971 MSD	EnviroQuant Chemstation G1701BA vB.01.00
Chromatograph—GC/MS---(VOC)---HP 5890 GCII and 5972 MSD	EnviroQuant Chemstation G1701BA vB.01.00
CT LAB	
Spectrophotometer—ICP/MS---(CT)----Perkin Elmer Elan DRC II	
Chromatograph—GC/MS—(CT)— HP 6890 GC and 5973N MSD	
VIROLOGY/IMMUNOLOGY	
Roche MagNA PURE LC	Roche ver. 3.0
Qiagen BioRobot 9604	QIASoft 3.0
Kodak---i260 Digital Scanner	Teleform Scan Station Version 8.2
Roche---Light Cycler Real Time PCR	Light Cycler Software Version. 4.0
ABI---ABI 7000	Sequence Detection System Version 1.0
Abbott---Flexible Pippetting Center (Commander)	FPC System Version 2.5.1
Abbott---Parallel Processing Center (Commander)	None
Tecan---Genesis RSP 150	Logic Standard Software Version 2.5.1
Abbott---Imx (Automated Immunoassay	FPC Imx Interface Version. 2.5

Analyzer)	
Tecan---Diagnostic Assay Processor	None
Molecular Devices---Versamax EXT Reader	Softmax Pro. Ver 4.7
GenProbe---Leader HCt GenProbe Reader	Aptima Combo 2 Ver. 3.1.2.2
Sensophone---Temperature monitor	Sensophone 2000 Ver. 3.1
Applied Biosystems/Hitachi---3100 Genetic Analyzer	3100 Genetic Analyzer Data Collection Ver. 2.0
Biorad---GelDoc 2000	Bionumerics Ver 3.5, Quantity One Ver. 4.0
BioMerieux---Bio-Tek ELX-800 Reader (Software needs upgrade)	Status Symbol II C.10
CLINICAL MICROBIOLOGY	
Biolog---OmniLog Plus System	Omnilog Plus Ver WE, Release 1.1
Agilent Technologies---6890 Gas Chromatograph	MIDI Ver. 4.5
Biorad---GelDoc 2000	Bionumerics Ver 3.5, Quantity One Ver. 2.0
Varian---AA240Z Zeeman Atomic Absorption Spectrometer	SpectrAA Version 3.0
Becton Dickinson---Bactec MGIT 960	BD-Epi Center Advanced Data Management System Version 3.2
Becton Dickinson---Bactec 460	None
Beckman Coulter---Beckman System Gold HPLC	System Gold Ver GoldV810, Pirovette Ver 1.22, Instep Ver 1.10
CONSUMER HEALTH MICROBIOLOGY	
Charm Sciences	C2 software version 2.51
3M petrifilm	3M
DuPont Qualicon---BAX Syatem	BAX System Ver 1.64
ENVIRONMENTAL MICROBIOLOGY	
None	
BIOTERRORISM/PUBLIC HEALTH PREPAREDNESS	
Perkin Elmer---VICTOR 2 TRF (Time Resolved Fluorscence)	Version 2.0, Release 9.
Shimadzu GC 143 (Gas Chromatograph)	Shimadzu GC Solution Ver. 2.2
Roche---Light Cycler Real Time PCR	Light Cycler Software Version. 4.0
ABI---ABI 7000	Sequence Detection System Version 1.0 AB DNA Sequencer Analysis Ver 5.1.1
Molecular Devices---Versamax EXT Reader	Softmax Pro. Ver 4.7

3.5. Expected Future Overall Workflow

ISDH is planning a move to a new facility in 2006 that will enable the implementation of a new workflow. The diagram below is a high level overview of the anticipated workflow.


Submitters
Containers / Kit Preparation
Specimen/Sample Receiving, Processing & Distribution
Support Group
Lab IT Group (db maintenance)
QC/QA (to all operating function areas)
Report Distribution (mail, fax, electronic)
Media / Reagents
Lab Supply / Inventory
Microbiology
Chemical Terrorism / Bioterrorism
Chemistry
Test resulting and verification
CDC / Reference Labs

4. Technical Requirements

This section (**and Section 5 below**) identifies requirements or constraints that apply to the entire ISDH LIMS, herein referred to as 'the LIMS'. The LIMS includes any and all software, hardware and services delivered as a whole or as component parts of the proposed LIMS. Submitted proposals shall discuss how the delivered LIMS will address the specific needs of the ISDH facility that are outlined in this document, in addition to any other LIMS features that are proposed by the vendor. Omissions regarding features, performance, and/or functionality that are stated in this RFP as required and not otherwise addressed will be considered the responsibility of the LIMS vendor to provide.

Using the requirements Matrix at Attachment E the vendor must respond to each requirement with sufficient detail to conclusively explain if and how the requirement will be met. Those requirements that are desired but not mandatory will be preceded with the word *desired*.

4.1. Application Design

4.1.1. *desired* - The proposed application shall be browser-based running on Internet Explorer 6.0 or higher
4.1.2. All client components of the delivered LIMS shall be fully 32-bit compatible with Microsoft Windows 2000/XP or higher.
4.1.3. *desired* - The delivered LIMS shall be based on industry-standard, commercially available components and tools such as HTML/ASP editors.
4.1.4. *desired* - The application shall support Internet and Intranet connectivity

4.2. Database Design

4.2.1. The proposed database design shall consist of a relational model with data redundancy to meet the business process requirements, facilitate quick inquiry response times and minimize storage capacity needs.
4.2.2. The preferred database for all proposed LIMS solutions is Oracle 9i or 10g.

4.3. Network Requirements

4.3.1. *desired* - The proposed solution must provide for 24 X 7 system availability, fail-over capability and data redundancy.
4.3.2. *desired* - The primary design of the delivered LIMS shall be thin client.
4.3.3. Whenever possible the proposed system shall leverage existing ISDH infrastructure.
4.3.4. The awarded vendor will be expected to meet with ISDH staff to determine appropriate benchmarks as part of the contract negotiations.

4.4. Application Connectivity

4.4.1. *desired* - Application connectivity will be via the Internet for users outside of the ISDH network.

4.4.2. *desired* - ISDH employees will use the Intranet to connect within the ISDH network.
4.4.3. *desired* - TCP/IP is the required connectivity protocol.
4.4.4. *desired* - All communications over the Internet involving client data and/or user passwords must be made via SSL connections.

4.5. System Security

4.5.1. The delivered LIMS shall provide security to protect the integrity of the data.
4.5.2. The security measures shall be compatible with Oracle, Internet Explorer, and Windows 2000 or XP.
4.5.3. The LIMS shall be in full compliance with all the Federal and State of Indiana regulations pertaining to electronic transmission of patient and health information, standards and reagents at the time of implementation (HIPAA).

4.6. Central Database Security

4.6.1. The delivered LIMS shall provide configurable security for the central database.
4.6.2. Any method of accessing the central database, whether through the LIMS application or external programs, shall require a login identifier and password.
4.6.3. Passwords must be encrypted and expire on fixed schedules.
4.6.4. The security shall be capable of providing read-only, limited editing, and full access to the database and be configurable as to types of access granted to all objects within the central database.

4.7. LIMS Application Security

4.7.1. The delivered LIMS application shall provide configurable security for all users of the application, whether internal or external to ISDH.
4.7.2. Each user shall gain access to the application through the use of a login and password.
4.7.3. Passwords must be encrypted and expire on fixed schedules.
4.7.4. Security features must enable the laboratory management to control and track user access to specific application modules, data entry/edit/retrieval screens, onscreen display of sensitive data, etc.
4.7.5. User security must be configurable by the ISDH authorized personnel.
4.7.6. Extra security shall be provided for particularly sensitive areas such as Bio-terrorism.
4.7.7. Security shall be provided down to the test code level for Bio-terrorism.
4.7.8. The system must provide a configurable automatic time out function based on keyboard or mouse inactivity.
4.7.9. All electronic transfers of data must be HIPAA compliant.

4.7.10. Configurable audit trail of edits made to lab tests, test requests, submitter information, etc. Identifies date/time, user and reason for change.

4.8. Server Resources Security

4.8.1. The delivered LIMS shall include configurable security for access to network resources such as printers, directories, and files.
4.8.2. The delivered LIMS shall use the existing I.E. and Oracle security functions.

4.9. Internet / Intranet Access Security

4.9.1. *desired* - The LIMS shall be delivered fully capable and compatible with access via the Internet.
4.9.2. *desired* - Access via the Internet must include appropriate security through firewall and virtual private network technology.

4.10. Technical Standards

4.10.1. Any web pages created for this project, whether static or dynamic, must meet the State of Indiana web page standards and the ISDH web page standards, especially as they regard to client accessibility features.
4.10.2. The proposed solution must meet the approval of the Indiana Information Technology Oversight Commission (ITOC).
4.10.3. The Vendor must demonstrate that the proposed solution has followed the FDA 2400 series guidelines and the GALP guidelines as it related to computerized systems.

4.11. Ad hoc Query Functionality

4.11.1. The proposed solution shall provide ad hoc query capabilities.
4.11.2. The proposed ad hoc query tools shall be able to access a query environment separate from the production environment.
4.11.3. The tools must operate with an easy-to-use GUI interface.
4.11.4. The basic function is to produce and manage structured query language (SQL) calls to the database.
4.11.5. The query tools shall work within required security rules.
4.11.6. Users shall be able to route query results to Microsoft Office 2000 products and a text file.

4.12. Office Applications

4.12.1. Laboratory workstations will use Microsoft Windows operating systems and Microsoft Suite office automation products. The delivered LIMS shall support transfer of data between the LIMS and office automation products

via Dynamic Data Exchange (DDE) or Object Linking and Embedding (OLE2).

4.12.2. Laboratory workstations will use Novell Groupwise Electronic Mail system. The delivered LIMS shall support the transfer of data via Groupwise.

4.13. Portable Device Integration

4.13.1. *desired* - It is desirable to have the capability to integrate into the proposed LIMS field data information captured using portable devices.

4.14. Document Imaging/Photo File Integration

4.14.1. The application shall have the capability to interface to a document imaging and photo application to retrieve the applicable stored image in context with the transaction, e.g., retrieving the correct submission form using the sample identification number, attaching a photo to a result.

4.15. Backup and Recovery

4.15.1. The vendor is required to suggest scenarios where incremental backups, full backups or dataset extracts are appropriate. These backup processes shall be automated.

4.15.2. Vendors must supply a detailed back up and recovery implementation plan.

5. FUNCTIONAL REQUIREMENTS

5.1. Container/Package/Kit Preparation and Shipping

ISDHL manages inventory items needed to supply submitters with predefined kits/containers needed for testing. The workflow includes kit order processing, assembly, and shipping.

5.1.1. Kit component ordering and receiving

5.1.1.1. Ability to process proactive specimen/sample schedules and set delivery dates and quantities

5.1.1.2. Ability to track inventory status and create replenishment orders for kit components based on assembled kit shipping schedule

5.1.1.3. Ability to record kit/container expiration dates

5.1.1.4. Receive component orders and increment stock inventories

5.1.2. Process submitter orders

5.1.2.1. Ability to create order packing slips for kit shipment to specific submitter locations based on proactive specimen/sample schedule delivery dates

5.1.2.2. Ability to receive and process kit orders directly from submitters either electronically or manually submitted
5.1.2.3. Ability to alert order processor that records indicate order requestor has sufficient quantity on hand based on number of test requests received by the laboratory
5.1.2.4. Ability to create labels (with definable format and data elements) needed for the proper processing of the containers upon receipt by the ISDH Labs
5.1.2.5. Ability to create submitter kit invoice information for prepayment or payment subsequent to shipping for processing by billing function
5.1.2.6. Ability to decrease inventory counts for order items pulled for shipping

5.1.3. Ship submitter orders
5.1.3.1. Ability to create order package labels and change order status for each specific submitter ship to location
5.1.3.2. Ability to record shipping information for tracking purposes
5.1.3.3. Ability to produce specimen submission forms
5.1.3.4. Desired - Ability to integrate with UPS shipping system bi-directionally

5.1.4. Forms management
5.1.4.1. Ability to electronically create and distribute new versions of forms and other documents necessary for the operation of the laboratory
5.1.4.2. Ability to manage the acquisition and distribution of forms and documents obtained in hard copy from external sources
5.1.4.3. Ability for users to create and modify on-line requisition form for use by the laboratories in ordering items from inventory

5.1.5. System outputs

5.1.5.1.1. Reports of kit/container shipments to submitters by submitter location and/or collector

5.1.5.1.2. Reports on kit outdating (kits in inventory that have expiration dates)

5.2. **Electronic Test Requests**

5.2.1. The delivered LIMS shall be able to process test requests received in PHIN standard HL7 message structure utilizing agreed upon coding standards (see PHIN web site http://www.cdc.gov/**phin/**)
5.2.2. Ability to create test request records in the LIM system directly from the electronic test request records, (this refers to the ability to parse a test request record), including specimen package contents (e.g., group

electronic test request submittals by physical specimen package where a package may contain multiple specimens for multiple subjects)

5.2.3. Ability to audit electronic test request records and return acknowledgement (ACK) messages to submitter verifying receipt and processing of the transmission

5.2.4. Ability to manually enter test request if received on paper form and perform independent verification on selected data fields by re-entry of the data in a second pass

5.2.5. Ability to link specimens/samples to corresponding electronic test request records via a LIM system display of unprocessed test requests for a given submitter, submittal date, and package ID

5.2.6. Ability to send PHIN compliant HL7 error messages to a submitter delineating which test request(s) have been rejected, and generate these messages automatically for all errors associated with a specific package once any problems have been recorded in the LIM system

5.2.7. Ability to create electronic transactions utilizing CDC PHIN HL7 compliant standards for order messages

5.3. Sample/Specimen Receipt/Test Ordering

Specimens arrive to the ISDH Labs by courier, mail, or walk-ins. Specimens are accompanied by Submission Forms that indicate the testing to be done. This function of test processing deals with test request and specimen/sample receipt and initial processing activities. Once this work is completed, the specimen/sample will have been routed to the specific laboratory and the test request entered in the LIM system. Any problems with test submittals will have been identified and the submitter notified.

5.3.1. Sample Login

5.3.1.1. Ability to login specimens and enter minimum information required to route specimens to lab workstation for timely testing

5.3.1.2. Ability to display specimen/sample receiving screens and accept data appropriate to the needs of each submission form

5.3.1.3. Ability to link multiple specimens from same individual at same time for same test from different source

5.3.1.4. Ability to automatically generate unique, sequential specimen identification numbers to be used as the primary identifier in tracking specimens through all stages of processing

5.3.1.5. Ability to generate mixed text and bar code labels of various sizes and bar codes for use in sample and batch identification

5.3.1.6. Ability to log in single and multiple specimens per form

5.3.1.7. Ability to accession specimens/samples with laboratory-wide unique numbers or individual laboratory specific unique numbers using a common accessioning protocol that allows real-time tracking of specimen progeny and siblings

5.3.1.8. Ability to input demographic and test request data by optical and/or barcode scanning, or manual keyboard data entry
5.3.1.8.1. Sample and/or submitter information must be configurable to allow laboratory to include fields such as address, city, county, location, site, etc.
5.3.1.9. Ability to assign status codes to specimens/samples (received, accepted, tested, etc.)
5.3.1.10. Ability to modify submittal forms and records to accommodate new testing requirements (e.g., WN, SARS, etc.) where users can add, activate, and deactivate specific tests
5.3.1.11. Ability to uniquely identify submitters, subjects, specimens/samples, test requests, and test results and unambiguously link test results with tests, tests requests with specimen/samples, specimen samples with the subject and associated data
5.3.1.12. Ability to create specimen/sample labels
5.3.1.13. Ability to create specimen/sample barcode labels using industry standard barcode formats
5.3.1.14. Ability to create postscript numbers for splits and aliquots of original specimen/samples
5.3.1.15. Ability to indicate on the sample label the type of preservative used
5.3.1.16. Ability to link raw product to manufactured product
5.3.1.17. Ability to indicate sample condition upon receipt.

5.3.2. Test Ordering
5.3.2.1. Ability to handle different test request information content for clinical versus environmental versus other miscellaneous specimen/samples and identify each request record as to whether it is a clinical, environmental or other test request in the LIM system
5.3.2.2. Ability to monitor test requests that require subsequent submittals
5.3.2.3. Ability to refer specimen/sample testing to external reference laboratories
5.3.2.4. Ability to assign a submitter priority to a specific test
5.3.2.5. Ability to assign priority by type of test
5.3.2.6. Ability to generate internal priority based on holding times, number of days since receipt, and other factors associated with specimen/sample
5.3.2.7. Ability to adjust priorities
5.3.2.8. Ability to adjust holding times based on extractions and other reasons
5.3.2.9. Ability to divert specimens/samples to another area in-house based on a trigger from a completed test for subsequent testing
5.3.2.10. Ability to record any specimen/sample problems that prevent testing and to cancel the request so that reporting of the action can occur

5.3.2.11. Ability to enter multiple request forms from the same submitter as a batch without repeating entry of common data
5.3.2.12. Ability to monitor test requests that require subsequent submittals such as previous positive results reported
5.3.2.13. Ability to enter request forms with multiple test requests
5.3.2.14. Ability to record whether or not hazard screening for BT samples (explosive, chemical radiological, etc.) has been done before receipt by laboratory
5.3.2.15. Ability to indicate minimum volume requirements by sample/container type
5.3.2.16. Ability to define default tests based on submitter
5.3.2.17. Ability to define and assign standard "panels" of tests, based on submitter, location or site.

5.3.3. Specimen/sample Routing
5.3.3.1. Ability to automatically indicate to which laboratory workstation a specimen/sample shall be directed
5.3.3.2. Ability to route specimens/samples associated with a test request submittal to multiple laboratories
5.3.3.3. Ability to route test requests to a centralized aggregation point for special projects or when an event prioritization occurs
5.3.3.4. Ability to route specimens/samples to external laboratories or agencies and create supporting documentation and packaging/shipping labels

5.3.4. Chain of Custody (Bio and Chemical Terrorism and Legal Samples)
5.3.4.1. Ability to associate the Submission Form and internal identification number to the associated chain of custody forms
5.3.4.2. Ability to record storage refrigerator or container ID, date stored, date removed for a specific specimen/sample ID
5.3.4.3. Ability to record dates and location when a specific specimen/sample was out of storage for testing process (could be linked to the test batch start and end times if recorded as a part of batch processing)
5.3.4.4. Ability to record specimen/sample disposition date and disposition code
5.3.4.5. Ability to move entire contents of a given storage location to another location (freezer mechanical failure for example)
5.3.4.6. Ability to make a tracking stop mandatory (i.e., a specimen must end up in a specific freezer)
5.3.4.7. Ability to identify and track individuals with specimen/sample custody
5.3.4.8. Ability to support and modify "chain of custody routing rules" by type of specimen/sample and use the rules for alerts when the actual chain of custody deviates from the standard rule set

5.3.4.9. Ability to access threat assessment information for each specimen/sample
5.3.4.10. Ability to flag a specimen/sample with a user defined code for "legal" or other desired code
5.3.4.11. Ability to track specimen/sample to forwarded locations external to lab

5.3.5. System outputs
5.3.5.1. Follow up letters and reports on outstanding subsequent test submittals (e.g., the notification of a submitter that a follow up specimen/sample is required when the first test was positive)
5.3.5.2. Report of specimen/sample rejections by rejection code and submitter for user specified time period
5.3.5.3. Report of specimens/samples with incomplete accessioning information
5.3.5.4. Report on test requests forwarded to external laboratories
5.3.5.5. Report on specimens/sample splits and aliquots
5.3.5.6. Reports on number of specimens accessioned by site, program, submitter, etc.
5.3.5.7. QC reports on what was changed, why, when, and by whom
5.3.5.8. Report of overdue specimens, including the ability for an authorized user to define when a specimen is overdue
5.3.5.9. Reports on test requests by submitter and timeframe
5.3.5.10. Report on a given specimen/sample's location from receipt to disposition by location and date
5.3.5.11. Tracking reports of known specimens/samples (QC organisms, etc.)
5.3.5.12. Report on the contents of a given refrigerator/freezer on any given date

5.4. Laboratory Receipt, Test Preparation and Preliminary Processing

Upon receipt in the laboratory, the specimens/samples are prepared for testing. This work includes creating any desired aliquots and any preliminary processing completed.

5.4.1. Test preparation and preliminary processing
5.4.1.1. Ability to create additional post scripted accessioning numbers for laboratory splits and aliquots
5.4.1.2. Ability to create and schedule a new test based on type of testing originally requested (a form of reflex testing)
5.4.1.3. Ability to update test request status and tracking record to track splits and aliquots
5.4.1.4. Ability to prioritize testing for a sample based on specified rules (e.g. priority of testing based on EPA requirements)
5.4.1.5. Ability to track analytical and prep batches back to a specimen

5.4.2. Specimen Inventory Management

5.4.2.1. Ability to manage the inventory of specimens/samples stored for pre- and post-processing (e.g. stored isolates)

5.4.3. System Outputs

5.4.3.1. Report of reflex and other subsequent testing organized by source test and reason

5.4.3.2. Report of patient name matches accepted and contents of combined lab records

5.5. Laboratory Test Processing – Testing, Results, and Verification

This function of test processing encompasses the testing, QC checks for validity of the results, the recording of the test results, and the generation of additional test requests where additional testing, based on the initial test results, is needed. In addition, in the case of QC failure, retesting requests are generated.

5.5.1. Batch Definition

5.5.1.1. Ability for user to define test instrument specific uniquely defined batches based on the specific needs of the analytical area

5.5.1.2. Ability to determine position of each standard, control, and patient specimen in the batch and specify specimens/samples for duplicate testing

5.5.1.3. Ability to track specimen/sample dilutions

5.5.1.4. Ability to specify whether test results are manually entered or are obtained electronically from an instrument. If test results are manually entered, the system shall automatically call up all items on the list sequentially or the whole worksheet to be resulted at operator request.

5.5.1.5. Ability to select all pending tests for worksheet generation, select a range of pending specimen/samples, if desired, (by date range, for example) and “tag” specific tests for worksheet generation sorted on a number of different criteria

5.5.1.6. Ability to create and print batch worksheet and allow user to regenerate (modify) the worksheet and add tests up to the point when the batch run results are entered.

5.5.1.7. Ability to prioritize test requests from test queue for inclusion in a batch.

5.5.1.8. Ability to display and/or print batch map (specimen/sample location by well/position)

5.5.1.9. Ability to create additional numerical sequence numbers and labels for consecutive specimen/sample numbering within a batch

5.5.1.10. Ability to create sample preparation batches and link them to sample analysis batches.

5.5.1.11. Ability to create tare batches for gravimetric determinations or radiochemistry yield determinations. These batches would then be used for net weight calculations.

5.5.1.12. Preparation and analysis batches will be created with appropriate QC standards, e.g. ICV, CCV, LFB, LFM, LRB, etc.

5.5.2. Equipment Interfacing

5.5.2.1. Ability to configure the system to send and receive data from the laboratory instrumentation.

5.5.2.2. Ability to send data to the laboratory instrument identifying samples, including QC samples, and the corresponding tests.

5.5.2.3. Ability to accept data from the laboratory instrumentation and link it to the results database.

5.5.2.4. Ability to identify samples for which there is no corresponding sample test record expecting result.

5.5.2.5. Ability to retrieve sample results multiple times and select the desired result.

5.5.3. Test result recording

5.5.3.1. Ability to present uniquely identified batch worksheet result entry screen in same sequence as batch.

5.5.3.2. Ability to allow manual entry of positive entries only and then default remainder of tests in batch to negative description.

5.5.3.3. Ability to select result description from user defined table for valid entries for each given test and apply the selected description to multiple tests in batch.

5.5.3.4. Ability to utilize tables containing the Systematized Nomenclature for Human and Veterinary Medicine (SNOMED) and LOINC for results descriptions where applicable or ability to map local codes used with the LIMS to SNOMED and LOINC codes.

5.5.3.5. Ability to select coded comments for inclusion with test result.

5.5.3.6. Ability to enter text field comments related to entire batch with the ability to code the comment as “internal lab use only” when appropriate so it doesn’t show on reports sent outside the lab.

5.5.3.7. Ability to remove “obvious outliers” when applicable.

5.5.3.8. Ability to support complex calculations (concentration calculations, etc.).

5.5.3.9. Ability to amend the specimen during reporting

5.5.3.10. Ability to enter text field comments related to specific test result.

5.5.3.11. Ability to insert photos as a result ensuring the photo cannot be altered.

5.5.3.12. Ability to highlight positive tests so they stand out on batch presentation.

5.5.3.13. Ability to capture ID of laboratory technician performing the test and creating the result entries along with date and time of analysis. Methods would include biometrics, etc.

5.5.3.14. Ability to allow easy recombination of individual determinations into multiple test suites (generally a tree type structure which may have multiple grouping levels).
5.5.3.15. Ability to average results on duplicate specimens/samples using the intra specimen sample variation as a QC parameter and store a record of all results.
5.5.3.16. Ability to track specimen/sample dilution factors back to undiluted specimens/samples and select the most appropriate test result (based on per test preferred concentration ranges) and select a correction of the dilution and record a corrected result.
5.5.3.17. Ability to monitor for and create alerts of "major" variations from normal.

5.5.4. Test QC verification
5.5.4.1. Ability to define test (batch) specific control ranges.
5.5.4.2. Ability to flag batch as suspect due to QC test values.
5.5.4.3. Ability to reject the batch based on QC failure and create appropriate audit trail.
5.5.4.4. Ability to tag each test in batch with QC failure reason.
5.5.4.5. Ability to display peer (second reading entry or review) validation screen.
5.5.4.6. Ability to enter peer validation edits and changes while keeping original recorded results with full audit trail for all changes/modifications.
5.5.4.7. Ability to enter peer reviewer ID for each batch.
5.5.4.8. Ability to create queue of batch test worksheets ready for peer or supervisory review.
5.5.4.9. Ability to display supervisor review screen.
5.5.4.10. Ability to enter supervisor validation edits and changes while keeping original and peer review recorded results.
5.5.4.11. Ability to release test batch for result printing once all required reviews have been completed.
5.5.4.12. Ability for a supervisor to over-ride a batch or individual test result tagged with a QC failure and to enter comments on why it was released despite the QC failure.

5.5.5. Requesting Retests and Additional Tests
5.5.5.1. Ability to trigger retest requirement and set up the tests in the test queue.
5.5.5.2. Ability to arbitrarily repeat any individual test request in a batch.
5.5.5.3. Ability to reuse same accessioning number for retest run.
5.5.5.4. Ability to link rejected test run to subsequent rerun.
5.5.5.5. Ability to create additional test requests associated with initial test results.
5.5.5.6. Ability to link initial test information to subsequent/additional testing.

5.5.5.7. Ability to reconcile current result with a previous result on same patient.

5.5.6. System outputs

5.5.6.1. Workload statistics based on submitter, test result, and time frame.

5.5.6.2. Ability to create report on pertinent run data for a specific batch including QC data associated with each test request.

5.5.6.3. QC reports on what was changed, why, and by whom.

5.5.6.4. Ways to alert technicians of specimens nearing predetermined critical action period (e.g., specimen stability, turn-around-time commitment, holding period).

5.6. Laboratory Test Report Preparation and Distribution

The recorded test results are used as the basis for the preparation and delivery of the test results report to the submitter and the creation and delivery of test results reports to other designated users.

5.6.1. Create and deliver test results to submitter

5.6.1.1. Ability to create PHIN-compliant HL7 electronic test report transactions utilizing SNOMED and LOINC coding standards.

5.6.1.2. Ability to transmit electronic test results either individually or by batch.

5.6.1.3. Ability to control which results, detailed or summary, shall be included in a report.

5.6.1.4. Ability to transmit print image so that submitter can print out hard copy in ISDH prescribed form including letterhead image.

5.6.1.5. Ability to send a test impression summary result that is an interpretation of multiple detailed test results.

5.6.1.6. Ability to transmit report directly from the LIMS to a fax machine.

5.6.1.7. Ability to transmit electronic test reports in secure format conforming to PHIN and HIPAA standards for privacy and security.

5.6.1.8. Ability to attach electronic signature to each electronic record.

5.6.1.9. Ability to print hard copy test report for mailing containing an electronic signature (one way is to attach the printed signature field onto the test record as the report is prepared for printing rather than having it as a standard text field in the print format).

5.6.1.10. Ability to indicate that the report is “preliminary,” “final,” “corrected,” or “amended” (CAP and CLIA requirements) and track multiple revisions to the same report.

5.6.1.11. Ability to sort printed hard copy test results by submitter prior to printing, and print a cover sheet for each submitter grouping.

5.6.1.12. Ability to create mailing labels for each submitter test report package.

5.6.1.13. Ability to update test request record to indicate report has been created.
5.6.1.14. Ability to create duplicate or amended test reports in either electronic or hard copy with indication that they are "duplicate" or "amended."
5.6.1.15. Ability to flag list of user-defined results requiring immediate submitter notification, including creation of call lists to the pre-defined submitter contact.
5.6.1.16. Ability to record notification contact information including date and time, person notified, PHL person making the contact, and the result(s) recorded.
5.6.1.17. Ability to define sample specifications by matrix or sample type, using a combination of test results, for use in reporting samples that pass or fail.
5.6.1.18. Ability to specify approval mechanisms per test or per submitter

5.6.2. Prepare test result tabulations for other qualified users.
5.6.2.1. Ability to qualify (i.e., grant permission to see) users by specific report.
5.6.2.2. Ability to create and maintain authorized distribution list for each report (since some reports can contain HIPAA-defined personal health information for which the laboratory would have to have formal business associate agreements).
5.6.2.3. Ability to read a registry or directory to get contact and/or protocol information for report recipients.
5.6.2.4. Ability to utilize a rules engine to determine the recipients for a message. The rules would dictate different recipients based on parameters ranging from: the type of test requested in the received test order; to the heightened urgency of the test as would be dictated during an event. This requirement would also include the ability to interface to link to the Health Alert Network.
5.6.2.5. Ability to tabulate test results by "positive" or total tests processed or a "rate positive" for a given geographic area by user over a specified time period through the use of a GIS tool.
5.6.2.6. Ability to release individual test results to a submitter prior to the completion of other related testing or recording of other test results in the same batch.

5.6.3. System outputs
5.6.3.1. Communicable disease reports to CDC, state agencies, and others as necessary.
5.6.3.2. Data exports to other reporting programs.
5.6.3.3. Reports of number of tests per instrument per time period.
5.6.3.4. Reports of number of tests performed by work unit by time period.
5.6.3.5. Reports of number of tests by method by time period.

5.6.3.6. Data extracts to FDA (food quality, food alterations, etc.).
5.6.3.7. Lab test kit performance reporting (reagent failure, performance problems, etc.).
5.6.3.8. Reports and data extracts for environmental health to EPA and others (SDWIS, STORET, etc.).
5.6.3.9. Ability to create "overlays" of data from both clinical and environmental testing by geographic area.
5.6.3.10. Reports on number of duplicate, amended, etc., reports issued.
5.6.3.11. Reports of number of tests per lab section by time period.
5.6.3.12. Reports of number of tests per lab section per submitter by time period.

5.7. Test Scheduling

This business process deals with prioritizing and processing the test workload already received. Scheduling factors include request urgency, specimen/sample holding time, and other factors relating to the timely processing of the test requests. In addition, the test schedule, in combination with longer-term workload projections, provides the basis for activating mutual assistance agreements.

5.7.1. Add requests received or additional tests generated in-house
5.7.1.1. Ability to add test requests and specimens/samples received and accepted by ISDH to specific test schedule.
5.7.1.2. Ability to add in-house generated tests to schedule.

5.7.2. Prioritize requests
5.7.2.1. Ability to assign a submitter priority to a specific test.
5.7.2.2. Ability to assign priority by type of test.
5.7.2.3. Ability to generate internal priority based on holding times, number of days since receipt, and other factors associated with specimen/sample.
5.7.2.4. Ability to adjust priorities.
5.7.2.5. Ability to organize test "queue" by priority.

5.7.3. Remove completed requests/transfers from active queue
5.7.3.1. Ability to automatically delete tests from the schedule once the result has been entered in the LIM system (and restore if needed).
5.7.3.2. Ability to manually delete a test request from the schedule/batch (and restore if needed) or delete an entire batch.
5.7.3.3. Ability to select tests for diversion to mutual assistance laboratory and create file of diverted tests.
5.7.3.4. *desired* - Ability to create packing lists and other documentation for diverted tests.
5.7.3.5. Ability to adjust holding times based on extractions and other reasons.

5.7.3.6. Ability to divert specimens/samples to another area in-house based on a trigger from a completed test for subsequent testing (e.g., isolation of *E coli* 0157 through PFGE).

5.7.4. Publish real-time test schedule

5.7.4.1. Ability to calculate daily processing capacity for each test; adjusted by instrument availability and personnel availability.

5.7.4.2. Ability to translate workload into N-day "rolling schedule" based on capacity limits where N is the number of days ahead of current date the user wants to include in the display.

5.7.4.3. Ability to track test loads in the schedule at the specific instrument level.

5.7.4.4. Ability to indicate which tests have been passed through to another laboratory (mutual assistance situation, etc.).

5.7.4.5. Ability to record test results for tests performed by another laboratory and indicate name of person who performed the test.

5.7.4.6. Ability to create subsequent test requests from a given test request.

5.7.4.7. Ability to flag overdue test requests based on schedule and notify submitter.

5.7.5. System outputs

5.7.5.1. Reports of test processing time by priority.

5.7.5.2. Test status reports.

5.8. Proactive Specimen/Sample Collection and Workload Projections

Specimen/sample collection schedules may be received from submitters either as a part of an agreement or independent of any formalized agreement. These specimen/sample collection schedules can involve kit distribution to multiple locations/collectors over multiple time frames. The kit distribution process and timing constitutes a "leading indicator" for subsequent test submissions. Overall workload projections are derived from adding "regular" submittal projections to the collection schedule derived projections.

5.8.1. Record collection kit distribution schedules in schedule system

5.8.1.1. Ability to manually enter specimen/sample collection schedules by submitter and collector kit delivery point.

5.8.1.2. Ability to electronically receive and process submitter collection schedules.

5.8.1.3. Ability to translate collection schedule into anticipated test request receipt dates with the capability for a separate routine for each submitter.

5.8.1.4. Ability to create submitter collector specific kit delivery orders including volumes, shipping dates, and out dates.

5.8.1.5. Record test requests received against collection schedule.

5.8.1.6. Ability to identify receipt of test requests generated from the collection schedule.
5.8.1.7. Ability to adjust workload projections by deducting the test requests received from the collection schedule.

5.8.2. Update anticipated future workload projections
5.8.2.1. Ability to present adjusted workload projects as new collection schedules are added and tests received are deducted.
5.8.2.2. Ability to have "real-time" current schedule available online for selected users.
5.8.2.3. Ability to create and add projections of "regular" workload by test for inclusion in the overall workload projections.

5.8.3. System outputs
5.8.3.1. Report of Current Specimen/Sample Collection Schedule by individual submitter or for all submitters.
5.8.3.2. Report of Current Test Workload by date and specific test.
5.8.3.3. Report of Current Kit Distribution orders by submitter, collector and time period.

5.9. *Desired* - Media, Reagent, Stains, Controls, etc. Manufacturing

Receive and process orders from internal laboratories and replenishment orders from inventory control. The replenishment order may be for more plates, which would potentially cause a need for more media to be produced which would have a ripple effect back to the inventory business process.

5.9.1. Ordering
5.9.1.1. Ability to record orders.
5.9.1.2. Ability to schedule manufacturing run based on inventory counts and orders.
5.9.1.3. Ability to flag minimum quantity levels for triggering of reorders.

5.9.2. Manufacture new lot
5.9.2.1. Ability to create electronic recipe book with ingredients for each recipe.
5.9.2.2. Ability to create raw ingredient needs for finished product lot, trigger appropriate orders from inventory, and record receipt from inventory.

5.9.3. QC lot and replenish inventory with new lot
5.9.3.1. Ability to record QC and expiration date against each lot.
5.9.3.2. Ability to increment inventory on hand quantity.
5.9.3.3. Ability to track batch failures when QC failure in laboratory is associated with manufactured or purchased lot.

5.9.3.4. Ability to create labels for marking incoming inventory as to date, time and hazard code (if any).
5.9.3.5. Ability to capture the internal QC result for QA purposes.

5.9.4. System outputs
5.9.4.1. QC Documentation.
5.9.4.2. Reports on manufactured items by time frame and use.
5.9.4.3. Cost reports for each manufactured item.

5.10. Lab Supply Inventory Management

ISDHL manages inventory items needed for direct support of the testing process. These inventory items are ordered from the internal laboratories and delivered to the bench.

5.10.1. Monitor inventory levels and create replenishment orders
5.10.1.1. Ability to monitor inventory levels and anticipated usage.
5.10.1.2. Ability to create replenishment orders.
5.10.1.3. Ability to update stock on hand and decrease outstanding order quantities based on quantities received.

5.10.2. Receive and fill internal laboratory and media kitchen orders
5.10.2.1. Receive and record orders (or receive them electronically from the individual laboratories or media kitchen).
5.10.2.2. Ability to decrease inventory counts for order items pulled for delivery to bench or shipped to other laboratories.
5.10.2.3. Ability to produce physical inventory worksheets and reconcile physical inventory counts with LIM system counts.
5.10.2.4. Ability to create inventory labels to track date received, time put in use, etc.

5.10.3. System outputs
5.10.3.1. Inventory item usage by item and cost (also person/section who used).
5.10.3.2. Inventory tracking of wet/dry/frozen ingredients.
5.10.3.3. Projections of inventory item usage by user defined time period and current proactive specimen/sample collection schedule, including estimated submitter inventory levels.
5.10.3.4. Cost history by item, cost center, and other factors.
5.10.3.5. Documentation of manufacturer QC for applicable items.
5.10.3.6. Reports of test cost profiles for all items supplied to laboratories.

5.11. Statistical Analysis and Surveillance

The key deliverable of ISDHL is accurate and timely test results. These results represent the major objective of the laboratory activity and the reason for its

existence. ISDH Laboratories can further contribute to the broader public health objective of assessment, policy development, and assurance in terms of identifying and responding to adverse health events caused by disease or environmental factors. These contributions can be broken out into two general categories: as a conduit for surveillance data and as a contributor to the understanding of the cause and impact of adverse test result patterns.

5.11.1. Non test specific data associated with test request submittals

5.11.1.1. Ability to capture and store patient name, address and demographic data submitted in conjunction with test requests from specific submitters.

5.11.1.2. Ability to capture and store risk factors, exposure information, and other patient characteristics associated with a test request from specific submitters.

5.11.1.3. Ability to electronically transmit non-test data elements to specified users.

5.11.1.4. Ability to electronically or manually capture and store the non test specific data.

5.11.2. Additional testing for typing and understanding of primary results

5.11.2.1. Ability to flag test results for which subsequent testing would be appropriate and automatically add follow up test requests to testing schedule.

5.11.2.2. Ability to link the subsequent test results to the primary test report.

5.11.2.3. Ability to build business rule tables for use in flagging.

5.11.3. Analysis

5.11.3.1. Ability to create positive test results as rates (positives related to total submittals).

5.11.3.2. Ability to analyze positive test patterns by type of test.

5.11.3.3. Ability to present combinations of clinic and environmental tests by geographic location for clustering analysis.

5.11.3.4. Ability to create user defined extracts of test data for electronic transmittal to specified users utilizing a standard open file structure format such as comma delimited flat files.

5.12. Training, Education and Resource Management

The data required for the support of the LIM-system specific training, education, and resource management (data such as instrument preventive maintenance) shall be incorporated in the LIM system to effectively support the laboratory's data needs in this regard. The Training and Education Module shall include maintenance of employee (primarily laboratory technicians) training records and education experience, determining training needs, determining training opportunities, and scheduling training. The Resource

(Instrument) Management shall include maintenance of records for each instrument and instrument method if multiple methods are used on a given instrument, tracking instrument preventive and emergency maintenance, tracking next preventive maintenance date, and monitoring instrument usage.

5.12.1. Training and Education Record Management

5.12.1.1. Ability to create and maintain employee records pertaining to specialized training.

5.12.1.2. Ability to track employee immunization status.

5.12.1.3. Ability to create and maintain code tables for training activities.

5.12.1.4. Ability to create and maintain business rules associated with each training activity including time intervals between "refresher" sessions.

5.12.1.5. Ability to flag employee training records when additional training is required and create reminders.

5.12.1.6. Ability to forecast training needs for specified time period (for example, projections for next 12 months by type of training).

5.12.1.7. Determine training opportunities and schedule training.

5.12.1.8. Create calendar for training offerings that can be accessed by employees and submitters (for example, instructions on specimen/sample packaging and shipping) for self-enrollment.

5.12.1.9. Ability to record training received in laboratory supported training as well as external training attended.

5.12.1.10. Ability for employees to view their training records.

5.12.1.11. Create and schedule training specifically addressed to correct QC or QA problems.

5.12.2. Resource Management

5.12.2.1. Ability to create and maintain master records for each instrument and associated method and periodic verification of minimum detection limits.

5.12.2.2. Ability to analyze test /method volumes and create capacity/day for each instrument method.

5.12.2.3. Ability to track preventive and emergency maintenance activity by instrument, including average "down time" for a preventive maintenance and average down time per month associated with emergency maintenance.

5.12.2.4. Ability to schedule instrument preventative maintenance and associated down time.

5.12.2.5. Ability to record actual down time for preventive and emergency maintenance.

5.12.2.6. Ability to report on test volumes and times by instrument and method.

5.12.3. System outputs

5.12.3.1. Current training schedule and associated information.

5.12.3.2. Schedule of special education (as needed depending on QA problems) and intended audience.
5.12.3.3. Reports of available qualified personnel counts by instrument.
5.12.3.4. Electronic instrument availability schedule and utilize it in scheduling activities.
5.12.3.5. Instrument maintenance schedules.

5.13. Lab Certifications/Licensing Management

ISDH is responsible for the ongoing annual licensing of other laboratories in the state. This activity includes inspections, obtaining and verifying proficiency test results, and re-inspection when deficiencies are noted. The inspection cycle consists of scheduling inspections, both initial and annual, tracking proficiencies, performing the inspections and re-inspections if deficiencies are discovered, and issuing licenses.

5.13.1. Proficiency Testing
5.13.1.1. *Desired* - Ability to create and maintain records of each proficiency test provided by ISDH and the results reported from the using laboratories.
5.13.1.2. Ability to record results from proficiency testing supplied by other vendors/laboratories.
5.13.1.3. *Desired* - Ability to track records associated with out-of-state laboratories performing testing work within the jurisdiction of ISDH.

5.13.2. *Desired* - Initial laboratory licensing
5.13.2.1. Ability to create master file record for new applicant laboratory including specific capabilities the laboratory wants to be certified to perform.
5.13.2.2. Ability to track initial licensure requirement fulfillment.
5.13.2.3. Ability to schedule initial inspection visit and record inspection findings.
5.13.2.4. Ability to track initial inspection deficiencies, re-inspection scheduling, and re-inspection results.
5.13.2.5. Ability to support license issuance.

5.13.3. *Desired* - Annual Licensing
5.13.3.1. Ability to support creation of annual inspection schedule.
5.13.3.2. Ability to record annual inspection results including deficiencies.
5.13.3.3. Ability to support re-inspection process and recording of deficiency resolution.
5.13.3.4. Ability to support issuance of annual license.
5.13.3.5. Ability to maintain master record of each laboratory's testing capability and qualifications.

5.13.4. *Desired* - System outputs
- 5.13.4.1. Data sets for entry into regulatory reporting systems.
- 5.13.4.2. Variety of regulatory reports for CAP, CLIA, etc.
- 5.13.4.3. Proficiency test distribution schedule.
- 5.13.4.4. Oversight inspection schedules.
- 5.13.4.5. History reports by laboratory.
- 5.13.4.6. Inspection and oversight reports for various government agencies.

5.14. *Desired* - Customer Concerns/Suggestions

Customer and employee feedback in the form of suggestions, concerns, and complaints are a key source of information relating to the quality of an organization. Generally, in mature organizations this feedback is encouraged and validated by a process of careful review, investigation and consideration, as well as feedback to the customer or employee on actions taken as a result. The feedback must be received and recorded, investigated, some action taken, and the action reported back to the source of the feedback.

5.14.1. Receiving, Recording, and Investigation
- 5.14.1.1. Ability to record and classify concerns and complaints including source and nature.
- 5.14.1.2. Ability to assign and change person responsible for investigation.
- 5.14.1.3. Ability to "escalate" problem status.

5.14.2. Action Recording and Reporting
- 5.14.2.1. Ability to document the findings and recommendations.
- 5.14.2.2. Ability to monitor success of any corrective action.
- 5.14.2.3. Ability to escalate a problem to the supervisory level.
- 5.14.2.4. Ability to report findings and recommendations back to the source via letter or other means.

5.14.3. System outputs
- 5.14.3.1. Summaries of suggestions, complaints and feedback for use in QA measures.

5.15. Quality Control (QC) and Quality Assurance (QA)

The key element for QC and QA is the ability to support an integrated view of these business and quality measures. For QC this involves the ability to determine the applicable QC elements that were operative at the time any test was performed and to be able to retrieve the documentation references through the use of the LIM system if the information is stored on hard copy. Ultimately, the goal is to have electronic documentation complete with electronic signature capability. For QA the goal is the ability to capture the data elements that define each QA measure and make it easier for ISDH to

track and evaluate the QA measures.

5.15.1. Quality Control (QC)

5.15.1.1. Ability to create and maintain a master record for each QC test by instrument/method.

5.15.1.2. Ability to create and maintain a master instrument/test/method record for associated input QC parameters (media, reagents, etc.).

5.15.1.3. Ability to create and maintain a master instrument/test/method record for specimen sample condition tracking elements (temperature control, holding time, etc.).

5.15.1.4. Ability to link the QC records for QC test, associated input, and specimen/sample condition if not created in same database table.

5.15.1.5. Ability to capture SOP on each instrument/test/method along with effective dates for each version.

5.15.1.6. Ability to electronically capture all QC measure values as appropriate as a part of the testing business process.

5.15.1.7. Ability to manually enter QC measure values in cases where the measures are not included in the testing business process support (media manufacturing, etc.).

5.15.1.8. Ability for user to define the placement of QC and proficiency tests within a batch.

5.15.1.9. Ability to track QC measures and to create analyses by time period or individual tests.

5.15.1.10. Ability to perform a variety of data reduction capabilities including linear regression (straight line fit), Log (Logit), Four Parameter Logistic and Cubic Spline.

5.15.1.11. Ability to produce Levy-Jennings QC plots, as needed.

5.15.1.12. Ability to use Westgard rules to evaluate whether analysis is in or out of control. The rules must be able to be turned on or off as needed for each test performed as well as specifying which rules to use for each test. The rules must be able to be used on a real time basis for problem identification.

5.15.1.13. Ability to analyze information on unknown specimens/samples, spiked specimens/samples and duplicate specimens/samples.

5.15.1.14. Ability to create alerts when QC measures trend toward limits.

5.15.1.15. Ability to warn users that QC for one or more elements for a instrument/test/method has failed under either batch or individual test circumstances.

5.15.1.16. Ability to automatically reschedule all tests invalidated by a QC failure with manual over-ride by supervisory personnel.

5.15.1.17. Ability to create a report of all QC measures associated with a specific specimen/sample submission.

5.15.1.18. Ability to include electronic signatures for QC entries.

5.15.1.19. Prepped QC samples (LFB,LFM,LRB, etc) will be associated with samples in the same prep batch, independent of the analysis batch.

5.15.1.20. Unprepped QC samples (CCV, etc) will be related to samples in the same analysis batch based on proximity.
5.15.1.21. Other more complicated rules may be used to determine association of QC to samples based on matrix, delivery group, submitter, etc.
5.15.1.22. Acceptance criteria for QC samples may differ depending on matrix and submitter.
5.15.1.23. The system will be capable of generating complete CLP- like printed QC/analysis reports for sample delivery groups.

5.15.2. Quality Assurance (QA)
5.15.2.1. Ability to create and maintain master records for each QA measure.
5.15.2.2. Ability to electronically transfer QA data associated with other business process support files.
5.15.2.3. Ability to manually enter QA data not captured in the LIM system as a part of other process support.
5.15.2.4. Ability to track QA measures and create analyses by time period.
5.15.2.5. Ability to create alerts when QA measures trend toward limits.
5.15.2.6. Ability to trigger special reports when QA measures have exceeded acceptable limits.

5.15.3. System outputs
5.15.3.1. Reports of QC failures for specified timeframe by specific laboratory, instrument, test, and method.
5.15.3.2. QC reports for support of audit activities (CLIA, CAP, etc).
5.15.3.3. QC analysis reports on duplicate testing.
5.15.3.4. Reports/screen displays of standard operating procedures for each method with "read only" security controls.
5.15.3.5. QA reports for management by QA parameter.

6. Implementation and Transition Requirements

The proposal shall specify a plan for seamlessly implementing the proposed LIMS. The plan shall address the implementation, transition, training, documentation, and maintenance requirements.

6.1. Implementation

6.1.1. The selected LIMS vendor or their designated representative shall perform the initial installation of the LIMS including configuration, data conversion, and customization tasks.
6.1.2. Vendors shall provide, as part of their proposal, a path or sequence of events, including a timetable, for the completion of this effort. This discussion shall address the various worksheets, reporting formats, and other customized documentation required by the laboratory.

6.1.3. If the installation process is separate from the LIMS software in the response, a recommended path for completion of the installation process shall be included in any submitted proposal.

6.1.4. The Implementation/Transition plan shall address Vendor support tasks, expectations and schedules for transition of each module into production.

6.1.5. On-site Vendor support is required from the time the first module receives final signoff and is moved to production until the last module receives final signoff and is moved into production.

6.2. Acceptance Testing

6.2.1. Each module shall undergo Acceptance Testing prior to implementation from the designated user group.

6.2.2. The designated user group shall have at least ten (10) business days, per deliverable, in the project work plan to complete a review and to document their findings.

6.2.3. Based on the review findings, the designate user group shall grant approval, reject portions of or the complete document, request contractor revisions be made, or state the inability to respond to the deliverable until a future specified date.

6.2.4. The Vendor shall address findings within ten (10) business days and report appropriate solutions with a timeline if applicable.

6.2.5. Additional ten (10) business day periods shall be required by the designated user group for subsequent reviews whenever revisions are requested or a deliverable is disapproved.

6.3. Data Migration

ISDH understands that the vendor cannot provide a detailed description of exactly how data migration will be accomplished until they have examined the existing data. However, the vendor shall provide sufficient background and experiential information to give ISDH reasonable confidence that the task can be accomplished. The vendor shall indicate the tools and services they provide to assist with the data migration and conversion. The vendor shall indicate, in the price proposal section of the proposal, an estimated average price of similar data migration efforts.

6.4. Training

6.4.1. Training Plan

6.4.1.1. The Training Plan must include detailed descriptions and recommendations for the different types of training, instructors that will be utilized, the training materials to be used, equipment required, training time required and a detailed training schedule.

6.4.1.2. The delivered solution must include a training database of test cases for hands-on training for each module/Lab section.

6.4.1.3. Training must be on-site training at ISDH.

6.4.2. System Administrators' Training

6.4.2.1. The Vendor must provide a combination of formal and on-the-job training to system administrators throughout the development and implementation.

6.4.2.2. The system administrators' training shall enable the designated system administrators to manage operations of the system, in terms of access, security, trouble-shooting; to update code tables.

6.4.3. End-User Staff Training

6.4.3.1. The training material for end-user staff must be designed for hands-on use and for the users' future reference.

6.4.3.2. End-User training must include a training plan for all the various modules for the applicable laboratory departments.

6.4.3.3. The training must enable all users to be able to operate the new system.

6.4.4. Training Evaluation

6.4.4.1. The Vendor will be required to provide an evaluation mechanism, to determine whether training has successfully prepared users, trainers, and system administrators to use, train other users, operate and maintain the new system.

6.4.4.2. The training evaluation shall consist of pass/fail evaluation administered to trainees at the completion of a training class. This tool will be used to identify weaknesses of the training program and specific revisions that need to be made. If training is unsatisfactory, an alternative training plan will be placed into effect and the staff re-trained.

6.5. **Documentation**

6.5.1. The Vendor must provide complete and accurate documentation for all entities in the LIMS. This documentation must include, but is not limited to, data dictionaries, data models, meta-data, transformation rules and valid values.

6.5.2. On-line documentation that can be accessed by the user directly from the application screens is also required. This help feature must be accessible throughout the system to assist users in each stage of data entry, retrieval and specimen processing.

6.5.3. At a minimum, documentation for the system must include specific User documentation and Technical/Programmer documentation.

6.5.4. While it is expected that ISDHL will use the basic manuals already developed for this system, the major modifications to the system must also be documented.

6.5.5. The Vendor must utilize a documentation control system at all times to maintain the currency of all documentation until successful completion of system turnover.

6.6. User Manuals

6.6.1. User Manuals must include a detailed description and explanation of how the various modules of the system work and their functions.
6.6.2. The manuals must be provided in the form of both on-line "help" screens and desktop manuals.
6.6.3. The Vendor shall update the manuals as Vendor changes are made to the system.
6.6.4. User manuals must be in electronic format with capability to print.
6.6.5. Manuals must be easy to understand with clear explanations of screens and functions for non-technical users in how to access and update data, and how to generate and understand reports.
6.6.6. The manual must include training material and handouts that can be used in formal hands-on training classes.
6.6.7. The manual must be organized to match logical business functions and cross-referenced so that all online query explanations, reports, and update functions can be reviewed as a group.
6.6.8. The manual must provide explanations of all codes and values, including error codes and documented in terms of meaning, along with an explanation of "next step" action or error correction alternatives.
6.6.9. The manual must include desk-level procedures for all support functions for all users and include a cross-reference of this material with on-line help screens.
6.6.10. The manual must provide a data dictionary, which may be understood by non-technical users, with a general but thorough explanation of where the data comes from, where the data resides, what the data means, and who has update/delete authority.
6.6.11. The manual must describe all computational formulas utilized in the applications.
6.6.12. The manual must include instructions for requesting standard and ad-hoc reports and provide samples of reports and include narrative descriptions of each report.
6.6.13. The manual must include instructions for the operation of all workstation equipment and the use of the various systems components and include instructions for all manual procedures related to the system.

6.7. Project Staffing

6.7.1. The Vendor shall propose and supply résumés for all staff working on the project. The Vendor will be required to have key staff be on-site at the state's location during the entire testing phase, as well as other agreed upon times.

6.8. **Project Management**

6.8.1. The Vendor must submit a detailed work plan for each phase of the project clearly identifying the resources necessary to meet each project goal.

6.8.2. The Vendor's project management approach must include regularly scheduled project meetings and reporting requirements.

6.9. **System Maintenance**

6.9.1. The Vendor must include a maintenance agreement with renewal clause to include but not be limited to Help Desk Support, Version Upgrades, Documentation Updates, Bug Fixes, and Hourly Rates for Custom Application Changes.

6.9.2. The proposal shall specify the various support options included in an annual maintenance agreement and also what is included in the scope of the agreement and intended response times.